



United States of America

Confidence Building Measure Return covering 2015

Convention on the Prohibition of the Development, Production and Stockpiling of
Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on
April 15, 2016

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F		✓	1997
G			

Date: April 15, 2016

State Party to the Convention: United States of America

Date of ratification/ accession to the Convention: March 26, 1975

National point of contact: Mr. Christopher Park, Department of State

Inquiries may be directed to BWC_USCBM@state.gov.

Report of the United States of America to the United Nations Department for Disarmament Affairs

Pursuant to the procedural modalities agreed upon in April 1987 at the "Ad Hoc Meeting of Scientific and Technical Experts for States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," the United States of America submits the following information under Article V of the Convention:

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Confidence Building Measure A, Part 2

Exchanges of information on national biological defence research and development programmes

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List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens page 159

Appendix B

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Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2016

Exchange of data on research centres and laboratories

1. Name(s) of facility.

National Biodefense Analysis and Countermeasures Center (NBACC)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.

U.S. Department of Homeland Security Science and Technology Directorate
Operated by Battelle National Biodefense Institute LLC

3. Location and postal address.

8300 Research Plaza, Fort Detrick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.

U.S. Department of Homeland Security (DHS)
U.S. Department of Defense (DOD) - partly
U.S. Department of Justice (DOJ)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²).

BSL 4 Laboratory 980 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.
(<http://bnbi.org/>)

The types of agents registered for use at NBACC are BSL-2 toxins, BSL-2 gram positive and gram negative bacterial agents, BSL-2 viral agents, BSL-3 gram positive and gram negative bacterial agents, BSL-3 viral agents, and BSL-4 viral agents.

Exchange of data on research centres and laboratories

1. Name(s) of facility.

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.

U.S. Army Medical Research and Materiel Command

3. Location and postal address.

1425 Porter Street, Fort Detrick, Frederick, Maryland 21702-5011

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.

U.S. Department of Defense (DoD) – partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (DHHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

5. Number of maximum containment units³ within the research centre and/or laboratory, with an indication of their respective size (m²).

BSL 4 Laboratory =1186 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

USAMRIID conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents include vaccines, drugs, diagnostic capabilities, and various medical management procedures.

Additional information can be found at: <http://www.usamriid.army.mil/>

Exchange of data on research centres and laboratories

1. Name(s) of facility.

Centers for Disease Control (CDC), Office of Infectious Diseases (OID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.

Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

3. Location and postal address.

1600 Clifton Road N.E., Atlanta, Georgia, 30333

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.

U.S. Agency for International Development (USAID)
U.S. Department of Defense (DOD) – partly
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
U.S. Department of State (DOS)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²).

BSL-4 Laboratory = 136 m²
BSL-4 Laboratory = 271 m²
BSL-4 Laboratory = 136 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

Activities include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, evaluating vaccines and medical countermeasures, determining the natural history of infectious organisms, assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. Additional information can be found at: <http://www.cdc.gov/oid/>.

Biodefense activities include those with select agents (the select agents list is available at: <http://www.selectagents.gov/SelectAgentsandToxinsList.html>).

Exchange of data on research centres and laboratories

1. Name(s) of facility

Integrated Research Facility at Fort Detrick (IRF – Frederick)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company

National Institutes of Health, Department of Health and Human Services
Operated by Battelle Memorial Institute

3. Location and postal address

8200 Research Plaza, Frederick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services (HHS)

5. Number of maximum containment units³ within the research centre and/or laboratory, with an indication of their respective size (m²)

BSL 4 Laboratory = 1305 m²

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

The Integrated Research Facility at Fort Detrick in Frederick, Maryland (IRF-Frederick) is a component of the Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The mission of the IRF-Frederick is to manage, coordinate, and facilitate the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research emphasis is placed on elucidating the nature of high consequence pathogens. Additional information can be found at:

<http://www.niaid.nih.gov/about/organization/dir/irf/Pages/default.aspx>.

Exchange of data on research centres and laboratories

1. Name(s) of facility

Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company

National Institutes of Health (NIH), Department of Health and Human Services (HHS)

3. Location and postal address

903 South 4th Street, Hamilton, Montana 59840 United States

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services (HHS)

5. Number of maximum containment units³ within the research centre and/or laboratory, with an indication of their respective size (m²)

BSL-4 Laboratory = 1145 m²

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate

Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The RML mission is to play a leading role in the nation's efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Research at the Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML) is dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Additional information can be found at:

<http://www.niaid.nih.gov/about/organization/dir/rml/Pages/integratedResearchFacility.aspx>.

Exchange of data on research centres and laboratories

1. Name(s) of facility²

Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

2. Responsible public or private organization or company

The University of Texas Medical Branch

3. Location and postal address

301 University Boulevard, Galveston, Texas 77555

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Universities

U.S. Department of Agriculture (USDA)

Private Foundations

Pharmaceutical Industry

U.S. Department of Energy (DOE)

U.S. Department of Defense (DOD) - partly

U.S. Department of Homeland Security (DHS)

National Institutes of Health (NIH)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

BSL-4 Laboratory = 186 m² (Shope Laboratory)

BSL-4 Laboratory = 1022 m² (GNL Laboratory)

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate

The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines.

Additional information can be found at: <http://www.utmb.edu/gnl/>.

Exchange of data on research centres and laboratories

1. Name(s) of facility

The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology

2. Responsible public or private organization or company

Texas Biomedical Research Institute

3. Location and postal address

P.O. Box 760549, San Antonio, Texas 78245-0549

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services

Department of Defense (DOD) - partly

Department of Homeland Security (DHS)

Private Sector Companies

Private Donors

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

BSL 4 Laboratory = 114 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

The mission of the Laboratory is to develop vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents. Additional information can be found at: <http://www.txbiomed.org/about/extraordinary-resources/biosafety-level-4-laboratory>.

Exchange of data on research centres and laboratories

1. Name(s) of facility

Viral Immunology Center - National B Virus Resource Laboratory

2. Responsible public or private organization or company

Georgia State University

3. Location and postal address

P. O. Box 4118, Atlanta, Georgia 30302-4118

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence

Department of Health and Human Services

Georgia Research Alliance

Immunology Core Support

Elizabeth R. Griffin Research Foundation

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m²)

BSL 4 Laboratory = 60 m²

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate

The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with:

- **Early identification** - research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- **Appropriate antiviral drugs** - researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- **In the future, effective vaccines.**

Additional information can be found at <http://www2.gsu.edu/~wwwvir/Research/Index.html>

Form A, Part 2 (i)

BWC - Confidence Building Measure

National biological defence research and development programmes - Declaration

United States of America

April 15, 2016

National biological defence research and development programme: Declaration

Are there any national programmes to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such programmes would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

Yes

No

If the answer is Yes, complete Form A, part 2 (ii) which will provide a description of each programme

Form A, Part 2 (ii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Description

United States of America

April 15, 2016

National biological defence research and development programmes

The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the *National Strategy for Countering Biological Threats*, this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. These programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of their pathogenicity. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development work, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health needs. Efforts to improve medical product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and to clean up the site of a biological weapons attack have civilian applications that benefit public health services, such as epidemiological disease surveillance and environmental remediation.

To promote the benefits gained by these programs and to ensure that the research is available to the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

For more information on U.S. Government strategies related to biodefense, including biological threat preparedness and response, please consult:

- Management of Domestic Incidents (Homeland Security Presidential Directive 5 [HSPD-5]) and the related National Response Framework;
- Presidential Policy Directive 8: National Preparedness (PPD-8);
- National Strategy for Defense of United States Agriculture and Food (HSPD-9);
- National Biodefense Strategy (HSPD-10/National Security Presidential Directive-33 [NSPD-33]);
- Medical Countermeasures against Weapons of Mass Destruction (HSPD-18);
- Public Health and Medical Preparedness (HSPD-21);
- National Strategy to Combat Weapons of Mass Destruction (NSPD-17/HSPD-4);
- Executive Order 13527 (“Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures following a Biological Attack”); and National Strategy for Countering Biological Threats.

National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The Department of Defense Chemical and Biological Defense Program develops capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical, biological, and radiological (CBR-) threats as part of a layered, integrated defense. The Program is an integral contributor to a global and systems approach for Countering Weapons of Mass Destruction (CWMD), Global Health Security, and other pertinent mission areas.

The Program works to counter biological threats by providing complementary sets of sensors, protective equipment, and medical countermeasures to counter known and unknown threats, including novel and naturally occurring emerging infectious diseases that may also pose a biological weapons threat. Current research focuses on signaling mechanisms between host and bacterial cells; expanding capabilities for pre- and post-exposure therapeutics for bacterial biological select agents and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; and developing rapid and deployable detection assays for force protection as well as medical defenses against neurotoxins.

The Program also works on producing self-disinfecting and/or self-decontaminating materials as well as developing, producing, and fielding capabilities for sampling, detecting, and identifying biological agents.

Biological defense related work conducted by the Department of Defense is carried out by the military services and biological defense program-focused agencies. These include funding agencies and service laboratories within the Departments of the Air Force, Army, and Navy, and the Defense Threat Reduction Agency/Joint Science and Technology Office, the Joint Program Executive Office for Chemical and Biological Defense, and the Defense Advanced Research Projects Agency.

2. State the total funding for each programme and its source.

\$593,425,000 U.S. Department of Defense (DoD)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

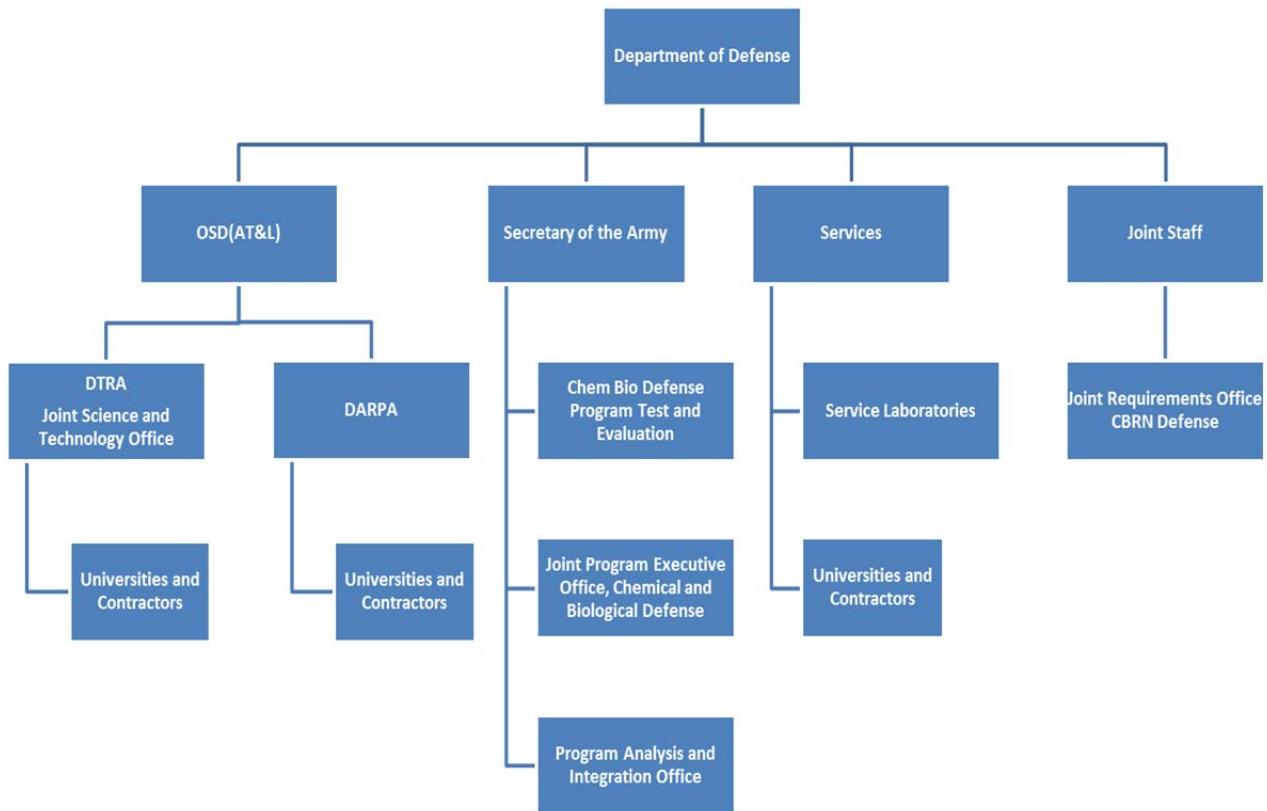
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

57%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

- Provide support and capabilities to protect the U.S. Armed Forces against biological warfare threats and emerging infectious diseases.
- Development and testing of vaccines, therapeutics, and diagnostic systems
- Development of self-disinfecting and/or self-decontaminating materials
- Development and testing of detection and identification methods, protective equipment, and decontamination systems

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



This chart reflects funding relationships

7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):

- Naval Medical Research Center (NMRC)
- Naval Research Laboratory (NRL)
- Naval Surface Warfare Center-Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory
- Lothar Salomon Test Facility (LSTF)
- U.S. Army Edgewood Chemical and Biological Center
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

National biological defense research and development programme: Description

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities: 1) assistance in the protection of the American water supply, and 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA's responders in the characterization and containment of contamination, and in the remediation of sites following terrorist attacks.

- 2. State the total funding for the programme and its source.**

\$8,500,000 U.S. Environmental Protection Agency (EPA)

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defense facilities?**

Yes

- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

35%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

To address capabilities related to EPA's indoor/outdoor remediation mission, NHSRC, through intramural and extramural avenues, conducts research related to characterization methods, risk assessment, decontamination methods, and waste management. Specifically the program develops and evaluates 1) sampling and analytical methods for environmental matrices, 2) decontamination methods for complex environments, and 3) treatment methods for solid and liquid waste. Supporting such capabilities, NHSRC has been addressing the fate and transport of biological agents and developing exposure assessment information and methods to support risk assessment decisions.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defense research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

The National Institutes of Health (NIH) biodefense program is supported by funding from HHS. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

2. State the total funding for each programme and its source.

\$76,068,526 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

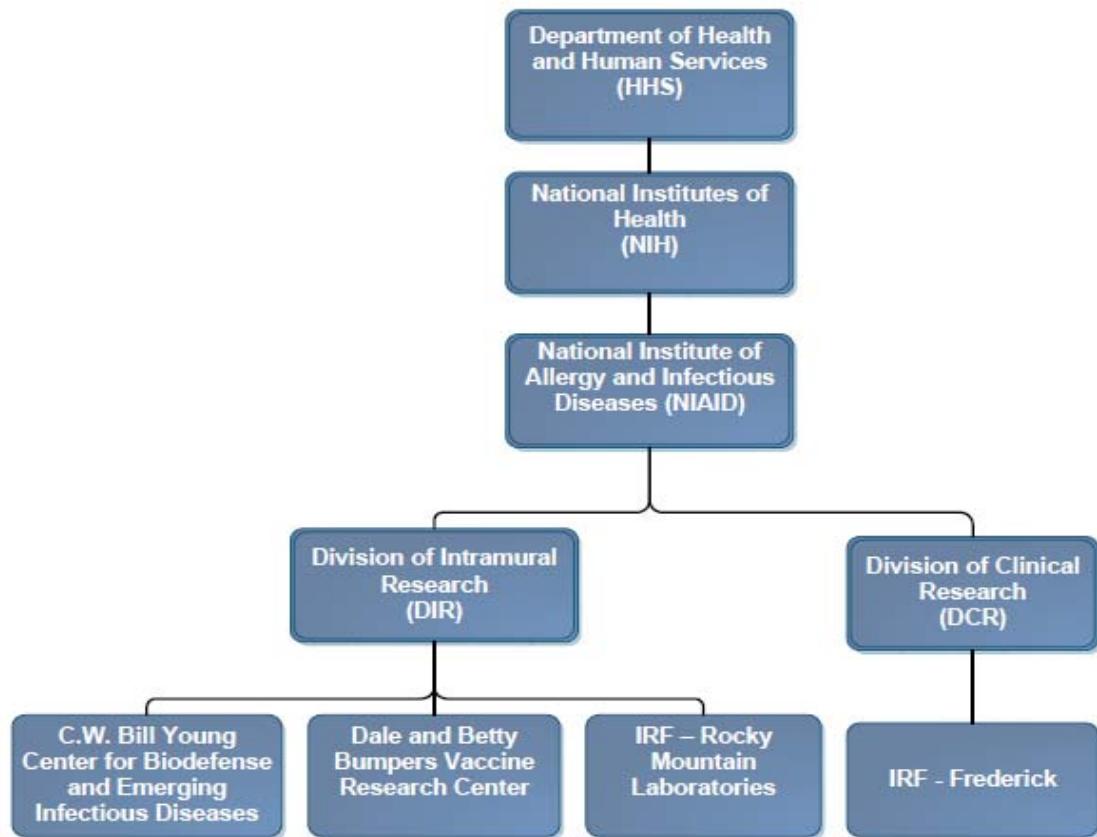
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

25%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

Battelle Memorial Institute facilitates scientific research at the Integrated Research Facility at Fort Detrick (IRF-Frederick), including refinement of animal models to facilitate countermeasure development, with direction from the IRF Scientific Steering Committee.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

Dale and Betty Bumpers Vaccine Research Center

Integrated Research Facility at Fort Detrick (IRF - Frederick)

Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML)

National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

The objective of the Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory within CDC's National Center for Environmental Health, Division of Laboratory Sciences is to develop toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins.

2. State the total funding for each programme and its source.

\$2,407,816 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

No

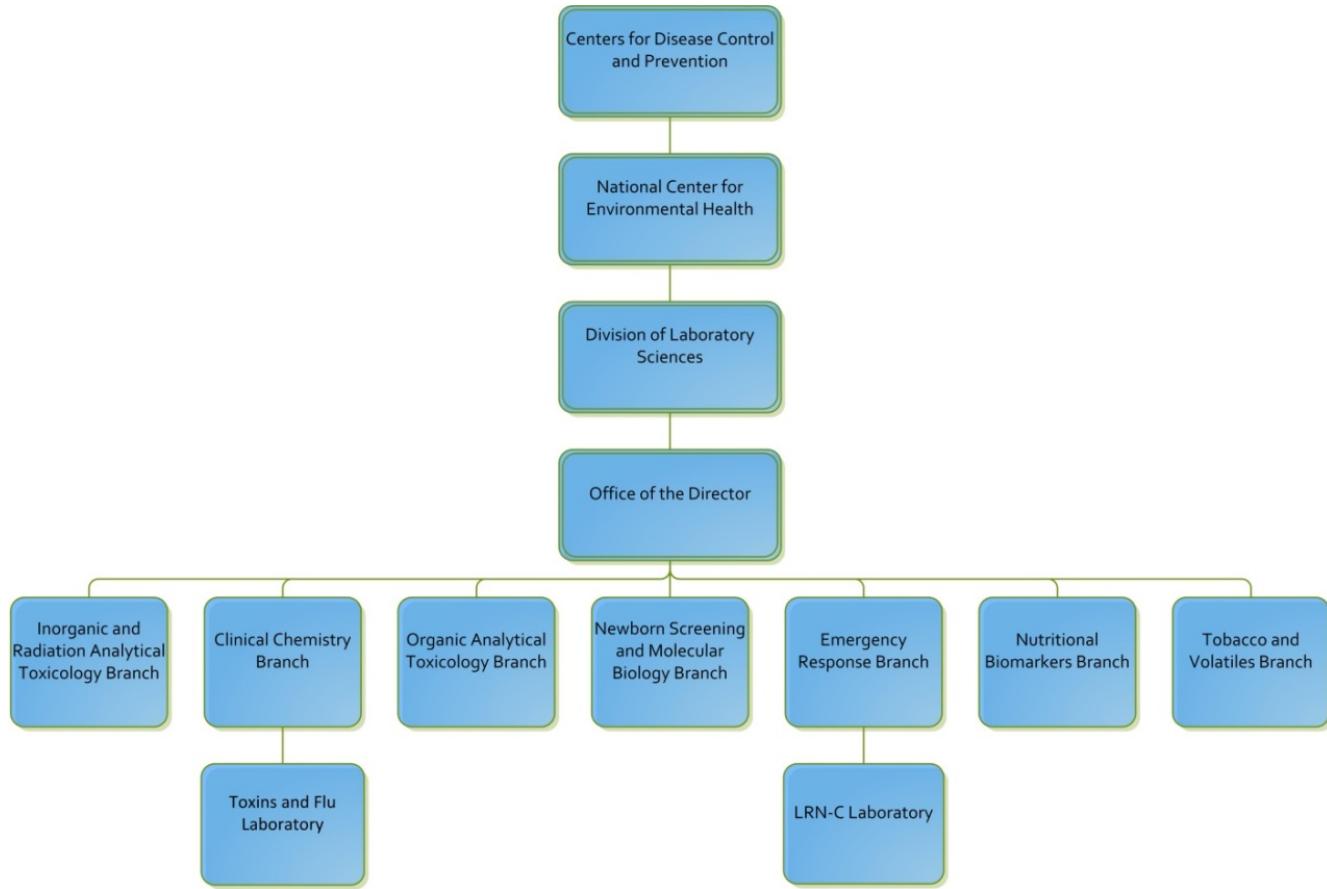
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

N/A

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

N/A

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS)

National biological defence research and development programmes: Description

1. State the objectives and funding of each programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxinology, physical protection, decontamination and other related research.

The activities of the CDC Office of Infectious Disease (OID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents. OID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

The select agents list is available at: <http://www.selectagents.gov>SelectAgentsandToxinsList.html>

2. State the total funding for each programme and its source.

\$30,868,649 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes

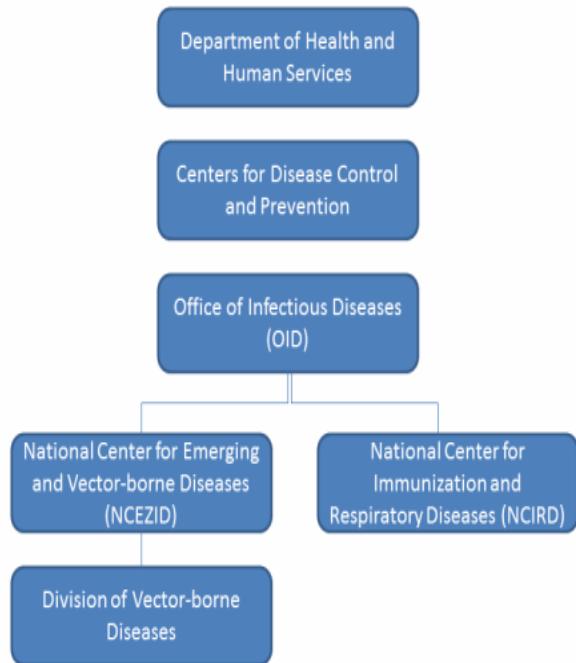
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?

5 %

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.

Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.

6. Provide a diagram of the organizational structure of each programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- CDC, OID, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins
- CDC, Office of Infectious Diseases (OID)

National biological defence research and development programmes: Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

Background

Foreign diseases of plants and animals represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, has devastating social and economic effects -- not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to wheat rust, Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Plant and Animal health officials define an exotic or foreign plant or animal disease as important infectious diseases of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. In addition, foreign animal diseases (FAD) are considered a threat to the U.S. when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled.

In the U.S., control usually means disease eradication. Disease eradication is currently accomplished by eliminating crops or animals, resulting in loss of foods, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the U.S. will be the loss of export markets. As we move into the 21st century, many new issues and factors are affecting prevention, control, management, and recovery from foreign disease outbreaks. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of plant and animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and characterization tools for prevention, control and eradication of foreign plant and animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and host responses is insufficient to rapidly control and eradicate disease outbreaks resulting from foreign plant and animal diseases incursions. Effective countermeasures to prevent, control and eradicate foreign plant and animal diseases are lacking or inadequate.

Strategic Objectives

- Establish Agriculture Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources
- Access to specialized high containment facilities to study zoonotic and emerging diseases
- Develop an integrated animal and microbial genomics research program
- Establish centers of excellence in animal immunology
- Launch a biotherapeutic discovery program providing alternatives to animal drugs
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology
- Develop internationally recognized OIE expert collaborative research laboratories
- Establish a best-in-class training center for our nation's veterinarians and scientists

- Develop a model technology transfer program to achieve the full impact of our research discoveries
- Determine basic knowledge of the biology, pathology, and epidemiology of selected Oomycete pathogens as the basis for development of improved control/management strategies

Research Needs

In order to control foreign animal disease, a wide variety of agent detection platforms needs to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in many countries, there is still much more fundamental knowledge of these agents that is required. There is still a lack of understanding in host range and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g. vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). Effective prevention and control tools need to be developed in order to prepare for the possibility of a foreign animal disease outbreak in the U.S. These could include tools for identifying suitable control strategies which take into account the short amount of time available and the cost of recovery from disease outbreaks. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles and for integrated methods of disease control (including vector control and animal management), which lead to a better capability to regain country disease-free status and retain economic sustainability.

Expected Outputs:

- Better anticipation of introduction of foreign animal diseases
- Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs
- Better capability to produce effective products to control and eliminate foreign animal diseases
- Real-time detection of agents in a wide range of farm matrices
- Searchable databases of genome and proteome information for major known FAD agents
- Improved ability to predict or anticipate emergence or introduction FAD agents
- Discovery of effective candidate biotherapeutics
- Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA)
- Viable integrated vector control strategies that minimize losses
- In-depth knowledge of pathogen biology, taxonomy, genetics, ecology, and pathology of emerging Oomycete pathogens that can be used to develop novel and effective exclusion, control and management strategies

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa; Orient Point, New York; Athens, Georgia; and Frederick, Maryland.

2. State the total funding for the programme and its source.

\$ 17,600,000 U.S. Department of Agriculture (USDA)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

No

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

Not Applicable

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

Not Applicable

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):

Foreign Disease-Weed Science Research Unit

Plum Island Animal Disease Center (PIADC)

Southeast Poultry Research Laboratory

National Animal Disease Center (NADC)

National biological defence research and development programmes: Description

1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.

Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key Department of Homeland Security (DHS) mission areas. This includes efforts to: prevent terrorist attacks, including biological attacks; prevent the unauthorized acquisition, importation, movement, or use of, *inter alia*, biological materials and capabilities within the United States; and reduce the vulnerability of critical infrastructure to terrorist attacks and other hazards. These efforts are further guided by the Homeland Security Presidential Directive – 10, “Biodefense for the 21st Century,” which outlines the four guiding pillars of the DHS Biodefense program: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery.

The goal of the DHS biodefense program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The DHS Biodefense program focuses on scenario modeling, agent release detection, training in responding to biological events, biological countermeasures research, development, testing, and evaluation (RDT&E) efforts, and on the transition of resultant technologies to operational use. The five main areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. federal agencies in overall coordination of national biodefense efforts.

Efforts conducted during 2015 include comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center included biological threat characterization, development of response plans and risk communication and at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, met in 2015 to review all relevant DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

2. State the total funding for the programme and its source.

\$95,400,000 U.S. Department of Homeland Security (DHS)

3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

Yes. The program funds work contracted to collaborating federal agencies (including defense agencies), national laboratories, private sector institutions and universities.

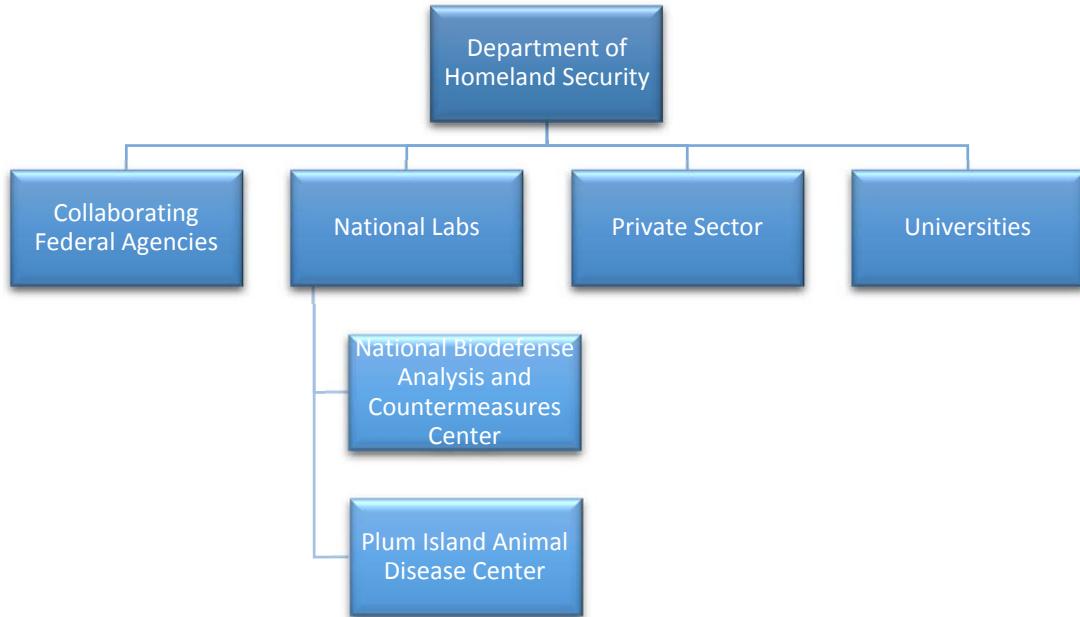
4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

100 %

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

Identical to answer provided in question 1.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A Part 2(iii):

National Biodefense Analysis and Countermeasures Center (NBACC)

Plum Island Animal Disease Center (PIADC)

Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2016

National biological defence research and development programme

The U.S. Government identified potential concerns associated with public release of information regarding highly pathogenic microorganisms and toxins at specific facilities. To balance these concerns with a desire to promote transparency, the U.S. public CBM return characterizes microorganisms and toxins studied at each facility on Form A, Part 2 (iii) as Select Agents and/or NIAID Category A pathogens. Furthermore, Appendix B lists the specific microorganisms and toxins studied for biodefense research and development at *all* facilities reported on Form A, part 2 (iii) below.

To maintain a high level of transparency to States Parties, the U.S. makes available, via the restricted-access portion of the ISU website, a Supplement containing information on microorganisms and toxins studied at each individual facility reported on Form A, part 2 (iii).

As stated in the U.S. working paper for the 2013 Meeting of Experts (BWC/MSP/2013/MX/WP.9), “the United States will report microorganisms and toxins that appear on either the Select Agent or the National Institute of Allergy and Infectious Diseases (NIAID) Category A pathogen lists, beginning in 2014.” These lists are reproduced in Appendix A for reference.

Biological Select Agents and Toxins (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Possession, use and transfer of Select Agents are regulated by the Select Agent Rules. Detailed information on Select Agents and their regulation can be found at: <http://www.selectagents.gov>.

The NIAID designated Category A pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Detailed information about NIAID Category A pathogens can be found at: <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx>.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

National Biodefense Analysis and Countermeasures Center (NBACC)

2. Where is it located (provide both address and geographical location)?

8300 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	1,282 m ²
BSL-3:	2,564 m ²
BSL-4:	980 m ²
Total laboratory floor area:	4,826 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 173

(ii) **Division of personnel:**
Military 0
Civilian 173

(iii) **Division of personnel by category:**
Scientists 33
Engineers 42
Technicians 57
Administrative and support staff 41

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Immunology, Molecular Biology, Toxicology, Veterinary Medicine, Virology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 173

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Homeland Security (DHS)

U.S. Department of Defense (DoD) – partly

U.S. Department of Justice (DoJ)

(vii) **What are the funding levels for the following program areas:**

Research \$ 7,049,860

Development \$ 13,947,786

Test and evaluation \$ 0

Total \$ 20,997,646

(viii) **Briefly describe the publication policy of the facility:**

The NBACC publication policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center (FFRDC) engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government laws, regulations and policies including: export control regulations under Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR); the Biological Weapons Convention (BWC), and internal U.S. Department of Homeland Security (DHS) policies. Prior to submittal to journals or release, all

publications are reviewed by NBACC and DHS for security, clarity, and accuracy with regard to the description of the work. The DHS Management Directive for Review of External Publications can be found at https://www.dhs.gov/sites/default/files/publications/mgmt_directive_2260.1_review_of_external_publications.pdf.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Berlin K, Koren S, Chin CS, Drake J, Landolin JM, Phillippy AM. Assembling large genomes with single-molecule sequencing and locality sensitive hashing. *Nat Biotechnol*. 2015 Jun; 33(6):623-30. doi: 10.1038/nbt.3238. Epub 2015 May 25. <http://www.nature.com/nbt/journal/v33/n6/abs/nbt.3238.html>
2. Evans CW, Atkins C, Pathak A, Gilbert BE, Noah JW. Benzimidazole analogs inhibit respiratory syncytial virus g protein function. *Antiviral Res*. 2015 Jun 24; 121:31-38. doi: 10.1016/j.antiviral.2015.06.016. PMID: 26116756. <http://www.ncbi.nlm.nih.gov/pubmed/26116756>
3. Falcinelli S, Gowen BB, Trost B, Napper S, Kusalik A, Johnson RF, Safronetz D, Prescott J, Wahl-Jensen V, Jahrling PB, Kindrachuk J. Characterization of the host response to pichinde virus infection in the Syrian golden hamster by species-specific kinome analysis. *Mol Cell Proteomics*. 2015 Mar; 14(3):646-57. doi: 10.1074/mcp.M114.045443. Epub 2015 Jan 8. <http://www.mcponline.org/content/14/3/646.full.pdf+html>
4. Fitch JP. Engineering a global response to infectious diseases. *Proc IEEE*. 2015 Feb; (103)2: 263-272, Doi: 10.1109/JPROC.2015.2389146. <http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=7067021>
5. Johnson SL, Baker AL, Chain PS, Currie BJ, Daligault HE, Davenport KW, Davis CB, Inglis TJ, Kaestli M, Koren S, Mayo M, Merritt AJ, Price EP, Sarovich DS, Warner J, Rosovitz MJ. Whole genome sequences of 80 environmental and clinical isolates of *Burkholderia pseudomallei*. *Genome Announc*. 2015 Jan/Feb; (3)1. e01282-14. Doi: 10.1128/genomeA.01282-14. <http://genomea.asm.org/content/3/1/e01282-14.full>
6. Labonte JM, Swan BK, Poulos B, Luo H, Koren S, Hallam SJ, Sullivan MB, Woyke T, Wommack KE, Stephanauskas R. Single-cell genomics-based analysis of virus-host interactions in marine surface bacterioplankton. *ISME J*. 2015 Nov; 9(11):2386-99. doi: 10.1038/ismej.2015.48. Epub 2015 Apr 7. <http://www.nature.com/ismej/journal/v9/n11/full/ismej201548a.html>
7. Landon VP, Bergman NH, Goodrich JS, Osborn J, Fitch JP. Institutional review of dual use research of concern to support a culture of responsibility. *J Bioterror Biodef*. 2015 Jan 6; (6)130. Doi: 10.4172/2157-2526.1000130. <http://www.omicsonline.org/open-access/institutional-review-of-dual-use-research-of-concern-to-support-a-culture-of-responsibility-2157-2526.1000130.php?aid=37855>
8. Londino JD, Lazrak A, Noah JW, Aggarwal S, Bali V, Woodworth BA, Bebok Z, Matalon S. Influenza virus m2 targets cystic fibrosis transmembrane conductance regulator for lysosomal degradation during viral infection. *FASEB J*. 2015 Jul 29; (7):2712-25. doi: 10.1096/fj.14-268755. Epub 2015 Mar 20. PMID: 25795456. <http://www.fasebj.org/content/29/7/2712.long>
9. Matharu DS, Flaherty DP, Simpson DS, Schroeder CE, Chung D, Yan D, Noah JW, Jonsson CB, White EL, Aubé J, Plemper RK, Severson WE, Golden JE. Optimization of potent and selective quinazolinediones: inhibitors of respiratory syncytial virus that block RNA-dependent RNA-polymerase complex activity. *J Med Chem*. 2014 Dec 26; 57(24):10314-28. doi: 10.1021/jm500902x. Epub 2014 Dec 4. PMID: 25399509. <http://pubs.acs.org/doi/10.1021/jm500902x>
10. McNutt P, Gut I, Hubbard K, Beske P. A novel method to prioritize rnaseq data for post-hoc analysis based on absolute changes in transcript. *Stat Appl Genet Mol Biol*. 2015 Jun 14; (3):227-41. Doi: 10.1515/sagmb-2014-0018. <http://www.degruyter.com/view/j/sagmb.2015.14.issue-3/sagmb-2014-0018/sagmb-2014-0018.xml>
11. Miller S, Cronin H. Developing a positive reinforcement training program for research sheep. *Lab Animal Sci Prof*. 2015 Jun 1; (3)2: 43-4. <https://www.aalas.org/articles/2015/06/01/developing-a-positive-reinforcement-training-program-for-research-sheep>

12. Ondov BD, Treangen TJ, Mallonee AB, Bergman NH, Koren S, Phillippy AM. Fast genome and metagenome distance estimation using minhash. *bioRxiv*. 2015 Oct 26; dx.doi.org/10.1101/029827. <http://biorkxiv.org/content/early/2015/10/26/029827>
13. Osborn J, Holt RK. Response to protocol review scenario: justify, justify, justify. *Lab Anim*. 2015 Jun; 44(6):204. doi: 10.1038/laban.783, doi:10.1038/laban.783 News. <http://www.labanimal.com/labanimal/journal/v44/n6/index.html>
14. Rasmussen L, Tigabu B, White EL, Bostwick R, Tower N, Bukreyev A, Rockx B, LeDuc JW, Noah JW. Adapting high-throughput screening methods and assays for biocontainment laboratories. *Assay Drug Dev Tech*. 2015 Jan-Feb; 13(1):44-54. doi: 10.1089/adt.2014.617. PMID: 25710545. <http://online.liebertpub.com/doi/abs/10.1089/adt.2014.617>
15. Santacroce J, Swearengen J, Weaver P. Novel approach for validating autoclave cycles for biomass in bsl-3 and bsl-4. *Appl Biosaf*. 2015 Oct 9; (20)3. https://my.absa.org/tiki-index.php?page=ABJ_2003
16. Schneider K, Wronka-Edwards L, Leggett-Embrey M, Walker E, Sun P, Ondov B, Wyman TH, Rosovitz MJ, Bohn S, Burans J, Kochel T. Psoralen inactivation of viruses: a process for the safe manipulation of viral antigen and nucleic acid. *Viruses*. 2015 Nov 12; 7(11):5875-88. doi: 10.3390/v7112912. <http://www.mdpi.com/1999-4915/7/11/2912>
17. Schreiber SL, Kotz JD, Li M, Aubé J, Austin CP, Reed JC, Rose NH, White EL, Sklar LA, Lindsley CW, Alexander BR, Bittker JA, Clemons PA, de Souza A, Foley MA, Palmer M, Shamji AF, Wawer MJ, McManus O, Wu M, Zou B, Yu H, Golden JE, Schoenen FJ, Simeonov A, Jadhav A, Jackson MR, Pinkerton AB, Chung TD, Griffin PR, Cravatt BF, Hodder PS, Roush WR, Roberts E, Chung DH, Jonsson CB, Noah JW, Severson WE, Ananthan S, Edwards B, Oprea TI, Conn PJ, Hopkins CR, Wood MR, Stauffer SR, Emmitt KA, NIH Molecular Libraries Project Team. Advancing biological understanding and therapeutics discovery with small-molecule probes. *Cell*. 2015 Jun 4; 161(6):1252-65. doi: 10.1016/j.cell.2015.05.023. Review. PMID: 26046436. <http://www.sciencedirect.com/science/article/pii/S0092867415005723>
18. Schroeder CE, Yao T, Sotsky J, Smith RA, Roy S, Chu YK, Guo H, Tower NA, Noah JW, McKellip S, Sosa M, Rasmussen L, Smith LH, White EL, Aubé J, Jonsson CB, Chung D, Golden JE. Development of (E)-2-((1,4-dimethylpiperazin-2-ylidene)amino)-5-nitro-n-phenylbenzamide, ml336: novel 2-amidinophenylbenzamides as potent inhibitors of Venezuelan equine encephalitis virus. *J Med Chem*. 2014 Oct 7; 57 (20), pp 8608–8621. <http://pubs.acs.org/doi/10.1021/jm501203v>
19. Treangen TJ, Maybank RA, Enke S, Friss MB, Diviak LF, Karaolis KR, Koren S, Ondov B, Phillippy AM, Bergman NH, Rosovitz MJ. Complete genome sequence of the quality control strain *staphylococcus aureus* subsp. *aureus* ATCC 25923. *Genome Announc*. 2014 Nov 6; 2(6): e01110-14. <http://genomea.asm.org/content/2/6/e01110-14.long>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms¹ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution investigations. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), Select Toxins (HHS), simulants, NIAID Category A pathogens.

Outdoor Studies: No outdoor studies performed

¹ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Plum Island Animal Disease Center (PIADC)

2. Where is it located (provide both address and geographical location)?

40550 Route 25, Orient Point, New York 11957

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	292 m ²
BSL-3:	18,046 m ²
BSL-4:	0 m ²
Total laboratory floor area:	18,338 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 403

(ii) **Division of personnel:**

Military	0
Civilian	403

(iii) **Division of personnel by category:**

Scientists	88
Engineers	6
Technicians	47
Administrative and support staff	262

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biological Science, Chemistry, Engineering, Microbiology, Molecular Biology, Computational Biology, Pathology, Veterinary Medicine

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 287

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture (USDA)
U.S. Department of Homeland Security (DHS)

(vii) **What are the funding levels for the following program areas:**

Research	\$ 6,000,000
Development	\$ 10,500,000
Test and evaluation	\$ 4,953,257
Total	\$ 21,453,257

(viii) **Briefly describe the publication policy of the facility:**

DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. USDA Agricultural Research Service (ARS) has several publication policies: 1) Policy Number 150.1 "Dissemination of Public Information by ARS," <http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf>; 2) Number 113.1 "Publishing (Print and Electronic), www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf; and 3) Number 152.1 "Procedures for

Publishing Manuscripts and Abstracts with Non-USDA Publishers (Outside Publishing)
<http://www.afm.ars.usda.gov/ppweb/pdf/152-01.pdf>

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Brito BP, Rodriguez LL, Hammond JM, Pinto J, Perez AM. Review of the global distribution of foot-and-mouth disease virus from 2007 to 2014. *Transbound Emerg Dis.* 2015 May 20 [Epub ahead of print].
<http://onlinelibrary.wiley.com/doi/10.1111/tbed.12373/full>
2. De Carvalho Ferreira HC, Pauszek SJ, Ludi A, Huston CL, Pacheco JM, Le VT, Nguyen PT, Bui HH, Nguyen TD, Nguyen T, Nguyen TT, Ngo LT, Do DH, Rodriguez L, Arzt J. An integrative analysis of foot-and-mouth disease virus carriers in Vietnam achieved through targeted surveillance and molecular epidemiology. *Transbound Emerg Dis.* 2015 Aug 24 [Epub ahead of print].
<http://onlinelibrary.wiley.com/doi/10.1111/tbed.12403/full>
3. Diaz-San Segundo F, Medina GN, Ramirez-Medina E, Velazquez-Salinas L, Koster M, Grubman MJ, de Los Santos T. Synonymous deoptimization of the foot-and-mouth disease virus causes attenuation *in vivo* while inducing a strong neutralizing antibody response. *J Virol.* 2015 Nov 18 [Epub ahead of print].
<http://jvi.asm.org/content/90/3/1298.abstract>
4. Fernandez-Sainz I, Ramanathan P, O'Donnell V, Diaz-San Segundo F, Velazquez-Salinas L, Sturza DF, Zhu J, de Los Santos T, Borca MV. Treatment with interferon-alpha delays disease in swine infected with a highly virulent CSFV strain. *Virology.* 2015 Sep; 483:284-90.
<http://dx.doi.org/10.1016/j.virol.2015.04.024>
5. Grau FR, Schroeder ME, Mulhern EL, McIntosh MT, Bounpheng MA. Detection of African swine fever, classical swine fever, and foot-and-mouth disease viruses in swine oral fluids by multiplex reverse transcription real-time polymerase chain reaction. *J Vet Diagn Invest.* 2015 Mar; 27(2):140-9.
<http://vdi.sagepub.com/content/27/2/140.abstract>
6. Krug PW, Holinka LG, O'Donnell V, Reese B, Sanford B, Fernandez-Sainz I, Gladue DP, Arzt J, Rodriguez L, Risatti GR, Borca MV. The progressive adaptation of a Georgian isolate of African swine fever virus to vero cells leads to a gradual attenuation of virulence in swine corresponding to major modifications of the viral genome. *J Virol.* 2015 Feb 15; 89(4):2324-32.
[Http://jvi.asm.org/content/89/4/2324.full](http://jvi.asm.org/content/89/4/2324.full)
7. Larocco M, Krug PW, Kramer E, Ahmed Z, Pacheco JM, Duque H, Baxt B, Rodriguez LL. Correction for Larocco et al., a continuous bovine kidney cell line constitutively expressing bovine alpha-v-beta-6 integrin has increased susceptibility to foot-and-mouth disease virus. *J Clin Microbiol.* 2015 Feb; 53(2):755. <Http://jcm.asm.org/content/53/2/755.full.pdf+html>
8. Medina GN, Montiel N, Sturza D, Diaz-San Segundo F, Ramirez-Medina E, Grubman MJ, de Los Santos T. Evaluation in cattle of fiber-modified adenovirus vector-vaccine against foot-and-mouth disease. *Clin Vaccine Immunol.* 2015 Nov 25. Pii: CVI.00426-15 [Epub ahead of print].
<http://cvi.asm.org/content/early/2015/11/20/CVI.00426-15.abstract>
9. Mohapatra JK, Pandey LK, Rai DK, Das B, Rodriguez LL, Rout M, Subramaniam S, Sanyal A, Rieder E, Pattnaik B. Cell culture adaptation mutations in foot-and-mouth disease virus serotype a capsid proteins: implications for receptor interactions. *J Gen Virol.* 2015 Mar; 96 (Pt 3):553-64.
<Http://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/vir.0.071597-0>
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13. Pacheco JM, Smoliga GR, O'Donnell V, Brito BP, Stenfeldt C, Rodriguez LL, Arzt J. Persistent foot-and-mouth disease virus infection in the nasopharynx of cattle; tissue-specific distribution and local cytokine expression. *Plos One* 2015 May 21; 10(5):e0125698. <Http://journals.plos.org/plosone/article?Id=10.1371/journal.pone.0125698>
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16. Ramanathan P, Zhu JJ, Bishop EA, Puckette MC, Hartwig E, Grubman MJ, Rodriguez LL. A colorimetric bioassay for high-throughput and cost-effectively assessing anti-foot-and-mouth disease virus activity. *Vet Immunol Immunopathol.* 2015 Mar 15; 164(1-2):74-8. <Http://www.sciencedirect.com/science/article/pii/S0165242715000112>
17. Ramirez-Carvajal L, Rodriguez LL. Virus-resistant pigs might help to stem next outbreak. *Elife.* 2015 Jul 29; 4. <Http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4518707/pdf/elife09790.pdf>
18. Ramírez-Carvajal L, Singh N, de Los Santos T, Rodríguez LL, Long CR. Depletion of elongation initiation factor 4e binding proteins by CRISPR/Cas9 enhances the antiviral response in porcine cells. *Antiviral Res.* 2015 Nov 22; 125:8-13 [Epub ahead of print]. <Http://www.sciencedirect.com/science/article/pii/S0166354215300231>
19. Singh N, Ramírez-Carvajal L, de Los Santos T, Golding MC, Long CR. Inhibition of EHMT2 induces a robust antiviral response against foot-and-mouth disease and vesicular stomatitis virus infections in bovine cells. *J Interferon Cytokine Res.* 2015 Sep 29. [Epub ahead of print] <Http://online.liebertpub.com/doi/pdf/10.1089/jir.2015.0006>
20. Stenfeldt C, Eschbaumer M, Pacheco JM, Rekant SI, Rodriguez LL, Arzt J. Pathogenesis of primary foot-and-mouth disease virus infection in the nasopharynx of vaccinated and non-vaccinated cattle. *Plos One.* 2015 Nov 23; 10(11):e0143666. Ecollection 2015. <Http://journals.plos.org/plosone/article?Id=10.1371/journal.pone.0143666>
21. Stenfeldt C, Pacheco JM, Singanallur NB, Ferreira HC, Vosloo W, Rodriguez LL, Arzt J. Clinical and virological dynamics of a serotype o 2010 south east Asia lineage foot-and-mouth disease virus in sheep using natural and simulated natural inoculation and exposure systems. *Vet Microbiol.* 2015 Jul 9; 178(1-2):50-60. <Http://doi.org/10.1016/j.vetmic.2015.04.004>
22. Stevens G, McCluskey B, King A, O'Hearn E, Mayr G. Review of the 2012 epizootic hemorrhagic disease outbreak in domestic ruminants in the united states. *Plos One.* 2015 Aug 5; 10(8). [http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0133359](Http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0133359)

23. Wilson WC, Daniels P, Ostlund EN, Johnson DE, Oberst RD, Hairgrove TB, Mediger J, McIntosh MT. Diagnostic tools for bluetongue and epizootic hemorrhagic disease viruses applicable to North American veterinary diagnosticians. *Vector Borne Zoonotic Dis.* 2015 Jun; 15(6):364-73.
[Http://online.liebertpub.com/doi/full/10.1089/vbz.2014.1702](http://online.liebertpub.com/doi/full/10.1089/vbz.2014.1702)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms² and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock, including foot-and-mouth disease, in the U.S. Technologies researched and developed are vaccines, antivirals, and diagnostic methods.

Microorganisms and/or Toxins Studied: Select Agents (USDA).

Outdoor Studies: No outdoor studies performed

² Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Lothar Salomon Test Facility (LSTF)

2. Where is it located (provide both address and geographical location)?

2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022-5006

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	710 m ²
BSL-3:	336 m ²
BSL-4:	0 m ²
Total laboratory floor area:	1,046 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 38

(ii) **Division of personnel:**

Military	0
Civilian	38

(iii) **Division of personnel by category:**

Scientists	31
Engineers	1
Technicians	4
Administrative and support staff	2

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology, Bacteriology, Biochemistry, Engineering, Immunology, Microbiology, Molecular Biology, Toxicology, Virology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes. Number: 9

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) – partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Justice (DOJ)

(vii) **What are the funding levels for the following program areas:**

Research	\$ 0
Development	\$ 0
Test and evaluation	\$ 1,582,000
Total	\$ 1,582,000

(viii) **Briefly describe the publication policy of the facility:**

Lothar Salomon's unique facilities and experienced staff of scientists, test officers, engineers, and technicians provide a full range of chemical and biological testing services, including the development of one-of-a-kind test capabilities, to meet customer requirements for new or developmental products. The

results from testing are documented in government publications, and their distribution is controlled by the test customer or sponsor. These results are not generally suitable for publication in peer-refereed journals.

All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf>) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523029p.pdf>).

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**
None (see above response to question 4.viii)

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms³ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Test battlefield detection and identification methods, protective equipment, and decontamination systems, including interferent testing of biological detectors, and develop/validate aerosol particle dispersion models to enhance countermeasure response. Additional information can be found at:

<http://www.dugway.army.mil>

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens, Simulants

Outdoor Studies: Yes - using simulants

³ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Naval Medical Research Center (NMRC)

2. Where is it located (provide both address and geographical location)?

8400 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	2,000 m ²
BSL-3:	0 m ²
BSL-4:	0 m ²
Total laboratory floor area:	2,000 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 61

(ii) **Division of personnel:**

Military	13
Civilian	48

(iii) **Division of personnel by category:**

Scientists	19
Engineers	0
Technicians	35
Administrative and support staff	7

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 43

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense – wholly

(vii) **What are the funding levels for the following program areas:**

Research	\$ 4,725,008
Development	\$ 0
Test and evaluation	\$ 0
Total	\$ 4,725,008

(viii) **Briefly describe the publication policy of the facility:**

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf>) and DoD Instruction 5320.29,

Security and Policy Review of DoD Information for Public Release
(<http://www.dtic.mil/whs/esd/osr/docs/523029p.pdf>).

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Chapman C, Henry M, Bishop-Lilly KA, Awosika J, Briska A, Ptashkin RN, Wagner T, Rajanna C, Tsang H, Johnson SL, Mokashi VP, Chain PSG, Sozhamannan S. Scanning the landscape of genome architecture of non-O1 and non-O139 *Vibrio cholerae* by whole genome mapping reveals extensive population genetic diversity. *PLoS One*. 2015 Mar 20; 10(3):e0120311. doi: 10:10.1371/journal.pone.0120311. eCollection 2015. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4368569>
2. Muller J, Gwozdz J, Hodgeman R, Ainsworth C, Kluver P, Czarnecki J, Warner S, Fegan M. Diagnostic performance characteristics of a rapid field test for anthrax in cattle. *Prev Vet Med*. 2015 Jul 1;120(3-4):277-82. doi: 10.1016/j.prevetmed.2015.03.016. Epub 2015 Apr 9. <http://www.ncbi.nlm.nih.gov/pubmed/25956134>
3. Clark DV, Kibuuka H, Millard M, Wakabi S, Luswa L, Tayler A, Eller MA, Eller LA, Michael NL, Honko AN, Olinger GG, Schoepp RJ, Hepburn MJ, Hensley LE, Robb ML. Long-term sequelae following Ebola virus disease. *Lancet Infect Dis*. 2015 Aug; 15(8):905-12. doi: 10.1016/S1473-3099(15)70152-0. Epub 2015 Apr 21. <http://www.ncbi.nlm.nih.gov/pubmed/25910637>
4. Larson MA, Nalbantoglu U, Sayood K, Zentz EB, Bartling AM, Francesconi SC, Fey PD, Dempsey MP, Hinrichs SH. *Francisella tularensis* Subtype A.II Genomic Plasticity in Comparison with Subtype A.I. *PLoS One*. 2015 Apr 28; 10(4):e0124906. 10.1371/journal.pone.0124906. eCollection 2014. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412822/>
5. Johnson SL, Daligault HE, Davenport KW, Coyne SR, Frey KG, Koroleva GI, Broomall SM, Bishop-Lilly KA, Bruce DC, Chertkov O, Freitas T, Jaissle J, Ladner JT, Rosenzweig CN, Gibbons HS, Palacios GF, Redden CL, Xu Y, Minogue TD, Chain PS. Genome sequencing of 18 *Francisella* strains to aid in assay development and testing. *Genome Announc*. 2015 Apr 30; 3(2): e00147-15. doi: 10.1128/genomeA.00147-15. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417685/>
6. Johnson SL, Daligault HE, Davenport KW, Jaissle J, Frey KG, Bishop-Lilly KA, Koroleva GI, Bruce DC, Coyne SR, Broomall SM, Li PE, Teshima H, Gibbons HS, Ladner JT, Palacios GF, Rosenzweig CN, Redden CL, Xu Y, Minogue TD, Chain PS. Complete genomes for 59 *Burkholderia* isolate genomes, both pathogenic and near-neighbor. *Genome Announc*. 2015 Apr 30; 3(2): e00159-15. doi:10.1128/genomeA.00159-15. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417688/>
7. Johnson SL, Daligault HE, Davenport KW, Jaissle J, Frey KG, Ladner JT, Broomall SM, Bishop-Lilly KA, Bruce DC, Coyne SR, Gibbons HS, Lo CC, Munk AC, Rosenzweig CN, Koroleva GI, Palacios GF, Redden CL, Xu Y, Minogue TD, Chain PS. Thirty-two complete genome assemblies of Nine *Yersinia* species, including *Y. pestis*, *Y. pseudotuberculosis*, and *Y. enterocolitica*. *Genome Announc*. 2015 Apr 30; 3(2): e00148-15. doi: 10.1128/genomeA.00148-15. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417686/>
8. Johnson SL, Daligault HE, Davenport KW, Jaissle J, Frey KG, Ladner JT, Broomall SM, Bishop-Lilly KA, Bruce DC, Gibbons HS, Coyne SR, Lo CC, Meincke L, Munk AC, Koroleva GI, Rosenzweig CN, Palacios GF, Redden CL, Minogue TD, Chain PS. Complete genome sequences for 35 biothreat assay-relevant bacillus species. *Genome Announc*. 2015 Apr 30; 3(2): e00151-15. doi: 10.1128/genomeA.00151-15. <http://www.ncbi.nlm.nih.gov/pubmed/25931591>
9. Johnson SL, Khiani A, Bishop-Lilly KA, Chapman C, Patel M, Verratti K, Munk AC, Bruce DC, Han C, Davenport KW, Chain P, Sozhamannan S. Complete genome assemblies for two single-chromosome *Vibrio cholerae* isolates, strains 1154-74 (Serogroup O49) and 10432-62 (Serogroup O27). *Genome Announc*. 2015 May 14; 3(3)e00462-15. doi: 10.1128/genomeA.00462-15.

<http://www.ncbi.nlm.nih.gov/pubmed/25977434>

10. Nyenswah TG, Fallah M, Calvert GM, Duwor S, Hamilton ED, Mokashi V, Arzoaquoi E, Dweh E, Burbach R, Dloughy D, Oeltmann JE, Monnan PK. Cluster of Ebola Virus Disease, Bong and Montserrado Counties, Liberia. *Emerg Infect Dis*. 2015 Jul; 21(7):1253-6. doi: 10.3201/eid2107.150511.
http://wwwnc.cdc.gov/eid/article/21/7/15-0511_article
11. Schully KL, Bell MG, Prouty AM, Gallovin MD, Gautam S, Peine KJ, Sharma A, Bachelder EM, Pesce JT, Elberson MA, Ainslie KM, Keane-Myers AM. Evaluation of a biodegradable microparticulate polymer as a carrier for *Burkholderia pseudomallei* subunit vaccines in a mouse model of melioidosis. *Int J Pharm*. 2015 Nov 30; 495(2):849-861. doi: 10.1016/j.ijpharm.2015.09.059. Epub 2015 Sep 28.
<http://www.ncbi.nlm.nih.gov/pubmed/26428631>
12. Nozadze M, Zhgenti E, Meparishvili M, Tverava L, Kiguradze T, Chanturia G, Babuadze G, Kekelidze M, Bakanidze L, Shutkova T, Imnadze P, Francesconi SC, Obiso R, Solomonia R. Comparative proteomic studies of *Yersinia pestis* strains isolated from natural foci in the Republic of Georgia. *Front Public Health*. 2015 Oct 16; 3:239. doi: 10.3389/fpubh.2015.00239. eCollection 2015.
<http://www.ncbi.nlm.nih.gov/pubmed/26528469>
13. Magaret A, Angus DC, Adhikari NK, Banura P, Kissoon N, Lawler JV, Jacob ST. Design of a multi-arm randomized clinical trial with no control arm. *Contemp Clin Trials*. 2016 Jan; 46:12-7. doi: 10.1016/j.cct.2015.11.003. Epub 2015 Nov 3.
<http://www.ncbi.nlm.nih.gov/pubmed/26542388>
14. Gardner SN, Frey KG, Redden CL, Thissen JB, Allen JE, Allred AF, Dyer MD, Mokashi VP, Slezak TR. Targeted amplification for enhanced detection of biothreat agents by next-generation sequencing. *BMC Res Notes*. 2015 Nov 16; 8:682. doi: 10.1186/s13104-015-1530-0.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4647626/>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms⁴ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The goal of the program is the development of rapid and deployable detection assays to protect deployed forces. During 2015 we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of new diagnostic assays and better treatment strategies against relevant infectious diseases. Additional information is available at

http://www.med.navy.mil/sites/nmrc/Pages/bd_main.htm

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), Select Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: None

⁴ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Naval Research Laboratory (NRL)

2. Where is it located (provide both address and geographical location)?

4555 Overlook Ave., SW, Washington, D.C. 20375

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	520 m ²
BSL-3:	0 m ²
BSL-4:	0 m ²
Total laboratory floor area:	520 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 33

(ii) **Division of personnel:**

Military	1
Civilian	32

(iii) **Division of personnel by category:**

Scientists	28
Engineers	1
Technicians	4
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Biophysics, Chemical Engineering, Chemistry, Immunology, Mechanical Engineering, Microbiology, Molecular Biology, Physics

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 4

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense – Wholly

(vii) **What are the funding levels for the following program areas:**

Research	\$ 3,959,000
Development	\$ 1,742,000
Test and evaluation	\$ 0
Total	\$ 5,701,000

(viii) **Briefly describe the publication policy of the facility:**

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.

Employees are encouraged to publish. Release of DoD publications is guided by DoD Directive 5230.09 (Clearance of DoD Information for Public Release,

<http://www.dtic.mil/whs/esd/osl/docs/523009p.pdf>) and DoD Instruction 5320.29 (Security and Policy Review of DoD Information for Public Release, <http://www.dtic.mil/whs/esd/osl/docs/523029p.pdf>) for publishing information related to biological defense efforts. Public release of unclassified technical information is subject to sponsor approval.

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Daniele MA, Boyd DA, Mott DR, Ligler FS. 3D hydrodynamic focusing microfluidics for emerging sensing technologies. Biosens Bioelectron. 2015 May 15; 67:25-34. <http://www.sciencedirect.com/science/article/pii/S0956566314004916>
2. Gaylord ST, Dinh TL, Goldman ER, Anderson GP, Ngan KC, Walt DR. Ultrasensitive detection of ricin toxin in multiple sample matrixes using single-domain antibodies. Anal Chem. 2015 May 22; 87(13):6570-6577. <http://pubs.acs.org/doi/abs/10.1021/acs.analchem.5b00322>
3. Hart MB, Sivaprakasam V, Eversole JD, Johnson LJ, Czege J. Optical measurements from single levitated particles using a linear electrodynamic quadrupole trap. Appl Opt. 2015 Nov 1; 54(31):F174-81. <http://www.ncbi.nlm.nih.gov/pubmed/26560606>
4. Hebert CG, Staton SJ, Hudson TQ, Hart SJ, Lopez-Mariscal C, Terray A. Dynamic radial positioning of a hydrodynamically focused particle stream enabled by a three-dimensional microfluidic nozzle. Biomicrofluidics. 2015 Mar 24; 9(2):024106. <http://www.ncbi.nlm.nih.gov/pubmed/25825621>
5. Kunapareddy N, Grun J, Lunsford R, Nikitin S, Wang Z, Gillis D. Multiwavelength Resonance Raman Characterization of the Effect of Growth Phase and Culture Medium on Bacteria. Appl Spectrosc. 2015 Aug; 69(8):966-71. <http://www.ncbi.nlm.nih.gov/pubmed/26163518>
6. Liu JL, Goldman ER, Zabetakis D, Walper SA, Turner KB, Shriver-Lake LC, Anderson GP. Enhanced production of a single domain antibody with an engineered stabilizing extra disulfide bond. Microb Cell Fact. 2015 Oct 9; 14(1):158. <http://microbialcellfactories.biomedcentral.com/articles/10.1186/s12934-015-0340-3>
7. Olson MA, Zabetakis D, Legler PM, Turner KB, Anderson GP, Goldman ER. Can template-based protein models guide the design of sequence fitness for enhanced thermal stability of single domain antibodies? PEDS. 2015 Sep 14; 28(10):395-402. <http://peds.oxfordjournals.org/content/28/10/395>
8. Raphael MP, Christodoulides JA, Byers JM, Anderson GP, Liu JL, Turner KB, Goldman ER, Delehanty JB. Optimizing nanoplasmonic biosensor sensitivity with orientated single domain antibodies. Plasmonics. 2015 May 26; 10(6):1649-1655. <http://link.springer.com/article/10.1007%2Fs11468-015-9969-3>
9. Turner KB, Liu JL, Zabetakis D, Brozozog-Lee A, Anderson GP, Goldman ER. Improving the biophysical properties of anti-ricin single-domain antibodies. Biotechnol Rep (Amst). 2015 June 15; 6:27-35. <http://www.sciencedirect.com/science/article/pii/S2215017X15000041>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms⁵ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The objectives of research at NRL are to develop and test reliable systems for the detection of chemical and biological (CB) warfare agents in order to provide early warning and contamination avoidance information. Additional information is available at <http://www.nrl.navy.mil/research/>.

Microorganisms and/or Toxins Studied: Simulants

Outdoor Studies: None

⁵ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory

2. Where is it located (provide both address and geographical location)?

6149 Welsh Road, Dahlgren, Virginia 22448

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	190 m ²
BSL-3:	26 m ²
BSL-4:	0 m ²
Total laboratory floor area:	216 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 184

(ii) **Division of personnel:**

Military	0
Civilian	184

(iii) **Division of personnel by category:**

Scientists	64
Engineers	46
Technicians	16
Administrative and support staff	58

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Aerospace Engineering, Chemical Engineering, Chemistry, Computer Engineering, Computer Science, Electronic Engineering, Industrial Engineering, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Toxicology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes Number: 30

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) – partly
Private Sector Companies
Internal (Laboratory Directed Research and Development [LDRD])
Other Governmental Agencies

(vii) **What are the funding levels for the following program areas:**

Research	\$ 1,331,000
Development	\$ 6,161,940
Test and evaluation	\$ 3,553,636
Total	\$ 11,046,576

(viii) Briefly describe the publication policy of the facility:

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf>) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523029p.pdf>)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Benedict A, Bansal N, Senina S, Hooper I, Lundberg L, de la Fuente C, Narayanan A, Gutting B, Kehn-Hall K. Repurposing FDA-approved drugs as therapeutics to treat Rift Valley fever virus infection. *Fronts in Microbiology*. 2015 Jul 08; 676(6): 1-23. doi: 10.3389/fmicb.2015.00676. <http://journal.frontiersin.org/article/10.3389/fmicb.2015.00676/abstract>
2. Buhr TL, Young AA, Barnette HK, Minter ZA, Kennihan NL, Johnson CA, Bohmke MD, DePaola M, Cora-Laó M, Page MA. Test methods and response surface models for hot, humid air decontamination of materials contaminated with dirty spores of *Bacillus anthracis* ΔSterne and *Bacillus thuringiensis* Al Hakam. *J Appl Microbiol*. 2015 Sep 21; 119(5):1263-77. doi: 10.1111/jam.12928. <http://www.ncbi.nlm.nih.gov/pubmed/26258399>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms⁶ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools, and consequence management planning. <http://www.navsea.navy.mil/Home/WarfareCenters/NSWCDahlgren.aspx>

Microorganisms and/or Toxins Studied: Select Agents (Overlap), NIAID Category A pathogens, Simulants

Outdoor Studies: None

⁶ Including viruses and prions.

National biological defence research and development programmes: Facilities**1. What is the name of the facility?**

U.S. Army Edgewood Chemical and Biological Center (ECBC)

2. Where is it located (provide both address and geographical location)?

5183 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5424

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	532 m ²
BSL-3:	177 m ²
BSL-4:	0 m ²
Total laboratory floor area:	709 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel** 105

(ii) **Division of personnel:**

Military	0
Civilian	105

(iii) **Division of personnel by category:**

Scientists	44
Engineers	0
Technicians	42
Administrative and support staff	19

(iv) **List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology, Aerospace Engineering, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Electronic Engineering, Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Physiology, Toxicology, Toxinology, Virology.

(v) **Are contractor staff working in the facility? If so, provide an approximate number.**

Yes. Number: 37

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U. S. Department of Defense (DoD) – Wholly

(vii) **What are the funding levels for the following programme areas:**

Research	\$763,000
Development	\$21,341,000
Test and evaluation	\$0
Total	\$22,104,000

(viii) **Briefly describe the publication policy of the facility:**

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international

professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:

AR 70-31 "Standards for Technical Reporting" http://www.apd.army.mil/jw2/xmldemo/r70_31/cover.asp
AR 360-1 "The Army Public Affairs Program" http://www.apd.army.mil/jw2/xmldemo/R360_1/cover.asp
AR 530-1 "Operations Security" http://www.apd.army.mil/jw2/xmldemo/r530_1/cover.asp

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf>) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523029p.pdf>).

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)

1. Angelini DJ, Moyer RA, Cole S, Willis KL, Oyler J, Dorsey RM, Salem H. The pesticide metabolites paraoxon and malaoxon induce cellular death by different mechanisms in cultured human pulmonary cells. *Int J Toxicol.* 2015 Sep 13; 34(5):441-43.
<http://ijt.sagepub.com/content/early/2015/07/13/1091581815593933.abstract>
2. Bigley AN, Mabanglo MF, Harvey SP, Rauschel FM. Variants of phosphotriesterase for the enhanced detoxification of the chemical warfare agent VR. *Biochemistry.* 2015 Sep 8; 54(35):5502-12.
<http://pubs.acs.org/doi/pdf/10.1021/acs.biochem.5b00629>
3. Katoski SE, Meyer H, Ibrahim S. An approach for identification of unknown viruses using sequencing-by-hybridization. *J Med Virol.* 2015 Sep; 87(9):1616-24.
<http://onlinelibrary.wiley.com/doi/10.1002/jmv.24196/abstract>
4. Adames NR, Wilson ML, Fang G, Lux MW, Glick BS, Peccoud J. Genolib: a database of biological parts derived from a library of common plasmid features. *Nucleic Acids Res.* 2015 Apr 29; 43(10):4823-32. <http://nar.oxfordjournals.org/content/early/2015/04/28/nar.gkv272.full.pdf>
5. Stromdahl EY, Nadolny RM, Gibbons JA, Auckland LD, Vince MA, Elkins CE, Murphy MP, Hickling GJ, Eshoo MW, Carolan HE, Crowder CD, Pilgard MA, Hamer SA. *Borrelia burgdorferi* not confirmed in human-biting *Amblyomma americanum* ticks from the southeastern United States. *J Clin Microbiol.* 2015 May; 53(5):1697-1704.
<http://jcm.asm.org/content/53/5/1697.full.pdf>
6. Klinzing DC, Choi SY, Hasan NA, Matias RR, Tayag E, Geronimo J, Skowronski E, Rashed SM, Kawashima K, Rosenzweig CN, Gibbons HS, Torres BC, Liles V, Alfon AC, Juan ML, Natividad FF, Cebula TA, Colwell RR. Hybrid *Vibrio cholerae* el tor lacking sxt identified as the cause of a cholera outbreak in the Philippines. *MBIO.* 2015 Apr; 6(2). <http://mbio.asm.org/content/6/2/e00047-15.full.pdf>
7. Kesavan J, Sagripanti JL. Evaluation criteria for bioaerosol samplers. *Environ Sci Process Impacts.* 2015 Mar 1; 17(3): 638-45. <http://pubs.rsc.org/en/content/articlepdf/2015/EM/C4EM00510D>
8. Kilianski A, Corriveau EJ, Liem AT, Rosenzweig CN, Haas JL, Kadavy DR, Minot SS, Willis KL. Bacterial and viral identification and differentiation by amplicon sequencing on the MinION nanopore sequencer. *GigaScience.* 2015 Mar 26; 4(12). <http://www.gigasciencejournal.com/content/pdf/s13742-015-0051-z.pdf>
9. Smith TJ, Hill KK, Xie G, Foley BT, Williamson CHD, Foster JT, Johnson SL, Chertkov O, Teshima H, Gibbons HS, Johnsky LA, Karavis MA, Smith LA. Genomic sequences of six botulinum neurotoxin-producing strains representing three clostridial species illustrate the mobility and diversity of botulinum neurotoxin genes. *Infection, Genetics and Evolution.* 2015 Mar 30; 102-13.

<http://www.sciencedirect.com/science/article/pii/S1567134814004481>

10. Martindale SM, Powers RH, Bell SC. Production of human metabolites by gastrointestinal bacteria as a potential source of post-mortem alteration of antemortem drug/metabolite concentrations. *Drug Test Anal.* 2015 Jan; 7(1); 75-82. <http://onlinelibrary.wiley.com/doi/10.1002/dta.1647/pdf>
11. Johnson SL, Daligault HE, Davenport KW, Jaissle J, Frey KG, Ladner JT, Broomall SM, Bishop-Lilly KA, Bruce DC, Gibbons HS, Coyne SR, Lo C-C, Meincke L, Munk AC, Koroleva GI, Rosenzweig CN, Palacios GF, Redden CL, Minogue TD, Chain PS. Complete genome sequences for 35 biothreat assay-relevant *Bacillus* species. *Genome Announc.* 2015; 3(2): e00151-15. doi:10.1128/genomeA.00151-15. <http://genomea.asm.org/content/3/2/e00151-15.full.pdf>
12. Johnson SL, Bishop-Lilly KA, Ladner JT, Daligault HE, Davenport KW, Jaissle J, Frey KG, Koroleva GI, Bruce DC, Coyne SR, Broomall SM, Li P-E, Teshima H, Gibbons HS, Palacios GF, Rosenzweig CN, Redden CL, Xu Y, Minogue TD, Chain PS. Complete genome sequences for 59 *Burkholderia* isolates, both pathogenic and near neighbor. *Genome Announc.* 2015; 3(2):e00159-15. doi:10.1128/genomeA.00159-15. <http://genomea.asm.org/content/3/2/e00159-15.full.pdf>
13. Johnson SL, Daligault HE, Davenport KW, Coyne SR, Frey KG, Koroleva GI, Broomall SM, Bishop-Lilly KA, Bruce DC, Chertkov O, Freitas T, Jaissle J, Ladner JT, Rosenzweig CN, Gibbons HS, Palacios GF, Redden CL, Xu Y, Minogue TD, Chain PS. Genome sequencing of 18 *Francisella* strains to aid in assay development and testing. *Genome Announc.* 2015; 3(2):e00147-15. doi:10.1128/genomeA.00147-15. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417685/>
14. Johnson SL, Daligault HE, Davenport KW, Jaissle J, Frey KG, Ladner JT, Broomall SM, Bishop-Lilly KA, Bruce DC, Coyne SR, Gibbons HS, Lo C-C, Munk AC, Rosenzweig CN, Koroleva GI, Palacios GF, Redden CL, Xu Y, Minogue TD, Chain PS. Thirty-two complete genome assemblies of nine *Yersinia* species, including *Y. pestis*, *Y. pseudotuberculosis*, and *Y. enterocolitica*. *Genome Announc.* 2015; 3(2):e00148-15. doi:10.1128/genomeA.00148-15. <http://genomea.asm.org/content/3/2/e00148-15.full.pdf>
15. Hirschberg DL, Betts K, Hutchins R, Emanuel P. DNA sequencing technologies within the chemical and biological defense enterprise: how to position the department of defense to maximize the use of these emerging technologies—JUPITER. ECBC-TR-1288. 2015 July. Accession Number : ADA619148 <http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA619148>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms (including viruses and prions) and or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: Development of non-medical defensive material against biological agents through research, development, and engineering of rapid detection, identification, decontamination methods as well as physical protection from biological threat agents. Additional information is available at <http://www.ecbc.army.mil/research/index.html>.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens, Simulants

Outdoor Studies: None

National biological defence research and development programmes: Facilities**1. What is the name of the facility?**

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?

2900 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010
(Main office for facility moved into new headquarters.)

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	300 m ²
BSL-3:	0 m ²
BSL-4:	0 m ²
Total laboratory floor area:	300 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 17

(ii) **Division of personnel:**

Military	0
Civilian	17

(iii) **Division of personnel by category:**

Scientists	7
Engineers	0
Technicians	10
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Molecular Biology, Pharmacology, Physiology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes. Number: 12

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) – wholly

(vii) **What are the funding levels for the following program areas:**

Research	\$ 2,017,755
Development	\$ 0
Test and evaluation	\$ 0
Total	\$ 2,017,755

(viii) **Briefly describe the publication policy of the facility:**

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include: AR 70-31 "Standards for Technical Reporting" http://www.apd.army.mil/jw2/xmldemo/r70_31/cover.asp; AR 360-1 "The Army Public Affairs Program" http://www.apd.army.mil/jw2/xmldemo/R360_1/cover.asp; and AR 530-1 "Operations Security" http://www.apd.army.mil/jw2/xmldemo/r530_1/cover.asp.

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osl/docs/523009p.pdf>) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osl/docs/523029p.pdf>)

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Beske, Phillip H., Bradford, Aaron B., Gryniovicki, Justin O., Glotfelty, Eliot J., Hoffman, Katie M., Hubbard Kyle S., Tuznik, Kaylie M., McNutt, Patrick M. Botulinum and tetanus neurotoxin-induced blockade of synaptic transmission in networked cultures of human and rodent neurons. *Toxicol Sci.* 2015 Nov 28. pii: kf254. [Epub ahead of print] <http://toxsci.oxfordjournals.org/content/early/2015/11/28/toxsci.kf254.long>
2. Beske, PH., Scheeler SM, Stephen, Adler M, McNutt PM. Accelerated intoxication of GABAergic synapses by botulinum neurotoxin A disinhibits stem cell-derived neuron networks prior to network silencing. *Front Cell Neuroscience.* 2015 Apr 23; 9(159). <http://journal.frontiersin.org/article/10.3389/fncel.2015.00159/abstract>
3. Bradford, AB, McNutt PM. Importance of being Nernst: Synaptic activity and functional relevance in stem cell-derived neurons. *World J Stem Cells.* 7(6), 899-921, 2015. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4515435/>
4. Hubbard K, Beske P, Lyman M, McNutt, P. Functional evaluation of biological neurotoxins in networked cultures of stem cell-derived central nervous system neurons. *J Vis Exp.* 2015 Feb 5; 96, doi: 10.3791/52361. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmid/25742030/>
5. Kumaran D, Adler M, Levit M, Krebs M, Sweeney R, Swaminathan S. Interactions of a potent cyclic peptide inhibitor with the light chain of botulinum neurotoxin A: Insights from X-ray crystallography. *Bioorg Med Chem.* 2015; 23(22): 7264-7273. <http://www.sciencedirect.com/science/article/pii/S0968089615301024>
6. McNutt PM, Beske P, Thirunavukkarsu N. Cell-based assays. In: *Biological Toxins and Bioterrorism* (eds. P. Gopalakrishnakone, M. Balali-Mood, L. Llewellyn, B.R. Singh), In *Toxicology*. New York: Springer, 247-271, 2015. <http://www.springer.com/us/book/9789400758681>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms⁷ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Discover and develop medical products and knowledge solutions against chemical and toxin threats through research, education and training, and consultation. USAMRICD performs comprehensive, basic scientific research using established and emerging technologies that support the transition of products to advanced development; develops education and training capabilities for military, interagency, domestic, and international personnel in the medical management of chemical casualties; and provides a venue for mutually beneficial collaboration with external investigators and interagency partners to conduct medical chemical defense research against chemical warfare agents and toxins. <https://usamricd.apgea.army.mil/>

Microorganisms and/or Toxins Studied: HHS Select Toxins

Outdoor Studies: None

⁷ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

2. Where is it located (provide both address and geographical location)?

1425 Porter Street, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	26,026 m ²
BSL-3:	3,139 m ²
BSL-4:	1,186 m ²
Total laboratory floor area:	30,351 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel** 919

(ii) **Division of personnel:**

Military	206
Civilian	713

(iii) **Division of personnel by category:**

Scientists	275
Engineers	8
Technicians	352
Administrative and support staff	284

(iv) **List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology, Biochemistry, Chemistry, Clinical Immunology, Entomology, Genetics, Immunology, Microbiology, Molecular Biology, Toxicology, Veterinary Medicine, Virology.

(v) **Are contractor staff working in the facility? If so, provide an approximate number.**

Yes. Number: 453

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense (DoD) – Partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (DHHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

(vii) **What are the funding levels for the following programme areas:**

Research	\$ 3,365,277
Development	\$ 51,409,181*
Test and evaluation	\$ 5,322,071
Total	\$ 60,096,529

*Includes reimbursables from Cooperative Research and Development Agreements and other Departments

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:

AR 70-31 "Standards for Technical Reporting"

http://www.apd.army.mil/jw2/xmldemo/r70_31/cover.asp

AR 360-1 "The Army Public Affairs Program"

http://www.apd.army.mil/jw2/xmldemo/r360_1/cover.asp

AR 530-1 "Operations Security"

http://www.apd.army.mil/jw2/xmldemo/r530_1/cover.asp

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523009p.pdf>) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (<http://www.dtic.mil/whs/esd/osr/docs/523029p.pdf>).

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months (include authors, titles and full references.)

1. Leguia M, Loyola S, Rios J, Juarez D, Guevara C, Silva M, Prieto K, Wiley M, Kasper MR, Palacios G, Bausch DG. Full Genomic Characterization of a Saffold Virus Isolated in Peru. *Pathogens*. 2015 Nov 20; 4(4):816-825 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4693166/>
2. Kuhn JH, Lauck M, Bailey AL, Shchetinin AM, et al. Reorganization and expansion of the nidoviral family Arteriviridae. *Arch Virol*. 2015 Nov 25. [Epub ahead of print]. <http://link.springer.com/article/10.1007/s00705-015-2672-z/fulltext.html>
3. Golden JW, Hammerbeck CD, Mucker EM, Brocato RL. Corrigendum to "Animal Models for the Study of Rodent-Borne Hemorrhagic Fever Viruses: Arenaviruses and Hantaviruses". *Biomed Res Int*. vol. 2015, Article ID 313190, 1 pages, 2015. doi:10.1155/2015/313190 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4637470/>
4. Riblett AM, Blomen VA, Jae LT, Altamura LA, Doms RW, Brummelkamp TR, Wojcechowskyj JA. A haploid genetic screen identifies heparan sulfate proteoglycans supporting Rift Valley fever virus infection. *J Virol*. 2015 Nov 18. pii: JVI.02055-15. [Epub ahead of print]. <http://jvi.asm.org/content/90/3/1414.long>
5. Chiang CY, Ulrich RL, Ulrich MP, Eaton B, Ojeda JF, Lane DJ, Kota KP, Kenny TA, Ladner JT, Dickson SP, Kuehl K, Raychaudhuri R, Sun M, Bavari S, Wolcott MJ, Covell D, Panchal RG. Characterization of the murine macrophage response to infection with virulent and avirulent *Burkholderia* species. *BMC Microbiol*. 2015 Nov 6; 15(1):259. doi: 10.1186/s12866-015-0593-3. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4636792/>
6. Kokashvili T, Whitehouse CA, Tskhvediani A, Grim CJ, Elbakidze T, Mitaishvili N, Janelidze N, Jaiani E, Haley BJ, Lashkhi N, Huq A, Colwell RR, Tediashvili M. Occurrence and Diversity of Clinically Important *Vibrio* Species in the Aquatic Environment of Georgia. *Front Public Health*. 2015 Oct 13; 3:232. doi: 10.3389/fpubh.2015.00232. eCollection 2015. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603242/>

7. Han Z, Madara JJ, Herbert A, Prugar LI, Ruthel G, Lu J, Liu Y, Liu W, Liu X, Wrobel JE, Reitz AB, Dye JM, Harty RN, Freedman BD. Calcium Regulation of Hemorrhagic Fever Virus Budding: Mechanistic Implications for Host-Oriented Therapeutic Intervention. *PLoS Pathog.* 2015 Oct 29; 11(10):e1005220. doi: 10.1371/journal.ppat.1005220. eCollection 2015 Oct.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4634230/>
8. Bixler SL, Goff AJ. The Role of Cytokines and Chemokines in Filovirus Infection. *Viruses.* 2015 Oct 23;7(10):5489-507. doi: 10.3390/v7102892. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632400/>
9. Mate SE, Kugelman JR, Nyenswah TG, et al. Molecular Evidence of Sexual Transmission of Ebola Virus. *N Engl J Med.* 2015 Dec 17; 373:2448-2454. DOI: 10.1056/NEJMoa1509773
<http://www.nejm.org/doi/full/10.1056/NEJMoa1509773>
10. Kuchuloria T, Imnadze P, Mamuchishvili N, Chokheli M, et al.. Hospital-Based Surveillance for Infectious Etiologies Among Patients with Acute Febrile Illness in Georgia, 2008-2011. *Am J Trop Med Hyg.* 2015 Oct 5. pii: 15-0400. [Epub ahead of print]. <http://www.ajtmh.org/content/94/1/236.long>
11. Honnold SP, Mossel EC, Bakken RR, Lind CM, Cohen JW, Eccleston LT, Spurges KB, Erwin-Cohen R, Glass PJ, Maheshwari RK. Eastern equine encephalitis virus in mice II: pathogenesis is dependent on route of exposure. *Virol J.* 2015 Sep 30; 12(1):154. doi: 10.1186/s12985-015-0385-2.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589026/>
12. Bounds CE, Kwikas SA, Kuehne AI, Brannan JM, Bakken RR, Dye JM, Hooper JW, Dupuy LC, Ellefson B, Hannaman D, Wu H, Jiao JA, Sullivan EJ, Schmaljohn CS. Human Polyclonal Antibodies Produced through DNA Vaccination of Transchromosomal Cattle Provide Mice with Post-Exposure Protection against Lethal Zaire and Sudan Ebolaviruses. *PLoS One.* 2015 Sep 30; 10(9):e0137786. doi: 10.1371/journal.pone.0137786. eCollection 2015. <http://dx.plos.org/10.1371/journal.pone.0137786>
13. Honnold SP, Mossel EC, Bakken RR, Fisher D, Lind CM, Cohen JW, Eccleston LT, Spurges KB, Erwin-Cohen R, Bradfute SB, Maheshwari RK, Glass PJ. Eastern equine encephalitis virus in mice I: clinical course and outcome are dependent on route of exposure. *Virol J.* 2015 Sep 29; 12(1):152. doi: 10.1186/s12985-015-0386-1. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4588493/>
14. Johnston SC, Lin KL, Twenhafel NA, Raymond JL, Shamblin JD, Wollen SE, Wlazlowski CB, Wilkinson ER, Botto MA, Goff AJ. Dose Response of MARV/Angola Infection in Cynomolgus Macaques following IM or Aerosol Exposure. *PLoS One.* 2015 Sep 28; 10(9):e0138843. doi: 10.1371/journal.pone.0138843. eCollection 2015.
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0138843>
15. Copeland AM, Van Deusen NM, Schmaljohn CS. Rift Valley fever virus NS(S) gene expression correlates with a defect in nuclear mRNA export. *Virology.* 2015 Sep 24; 486:88-93. doi: 10.1016/j.virol.2015.09.003. [Epub ahead of print].
<http://www.sciencedirect.com/science/article/pii/S0042682215003943>
16. Whitehouse CA, Bavari S, Perkins MD. United States FDA's emergency use authorization of Ebola virus diagnostics: current impact and lessons for the future. *Expert Rev Mol Diagn.* 2015; 15(10):1231-5. doi: 10.1586/14737159.2015.1077117. Epub 2015 Sep 7.
<http://www.tandfonline.com/doi/pdf/10.1586/14737159.2015.1077117>
17. Krakauer T. Inflammasome, mTORC1 activation, and metabolic derangement contribute to the susceptibility of diabetics to infections. *Med Hypotheses.* 2015 Dec; 85(6):997-1001. doi: 10.1016/j.mehy.2015.08.019. Epub 2015 Sep 6.
<http://www.sciencedirect.com/science/article/pii/S0306987715003254>
18. Johnson SL, Minogue TD, Daligault HE, Wolcott MJ, Teshima H, Coyne SR, Davenport KW, Jaissle JG, Chain PS. Finished Genome Assembly of Warm Spring Isolate Francisella novicida DPG 3A-IS. *Genome Announc.* 2015 Sep 17; 3(5):e01046-15. doi: 10.1128/genomeA.01046-15.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574370/>
19. Johnson SL, Minogue TD, Daligault HE, Wolcott MJ, Teshima H, Coyne SR, Davenport KW, Jaissle JG, Chain PS. Finished Genome Assembly of Yersinia pestis EV76D and KIM 10v. *Genome Announc.* 2015

Sep 17; 3(5):e01024-15. doi: 10.1128/genomeA.01024-15.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574367/>

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parameters during Ebola virus infection of rhesus macaques. *Viral Immunol.* 2015 Jan; 28(1):32-41. doi: 10.1089/vim.2014.0085. <http://online.liebertpub.com/doi/abs/10.1089/vim.2014.0085>

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms⁸ and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Develop medical countermeasures, including candidate vaccines, undergo diagnostic tests and drug or immunological therapies for biological agents, and perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at <http://www.usamriid.army.mil/>.

Agents Microorganisms and/or Toxins: Select Agents (HHS, Overlap), Select Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: None

⁸ Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Brookhaven National Laboratory

2. Where is it located (provide both address and geographical location)?

Brookhaven National Laboratory, Biology Department, Upton, New York 11973

(Located on William Floyd Parkway, County Road 46, 1.5 miles north of Long Island Expressway Exit 68)

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	18 m ²
BSL-3:	0 m ²
BSL-4:	0 m ²
Total laboratory floor area:	18 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 3

(ii) **Division of personnel:**

Military	0
Civilian	3

(iii) **Division of personnel by category:**

Scientists	3
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry, Structural Biology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense (DoD) – partly

Department of Health and Human Services (HHS)

(vii) **What are the funding levels for the following program areas:**

Research	\$ 689,000
Development	\$ 0
Test and evaluation	\$ 0
Total	\$ 689,000

(viii) **Briefly describe the publication policy of the facility:**

As a Department of Energy/Office of Science (DOE-SC) facility, BNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory

dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. BNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. BNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management:

<https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Eswaramoorthy S, Sun J, Li H, Singh BR, Swaminathan S. Molecular assembly of clostridium botulinum progenitor complex of type E. *Sci Rep.* 2015 Dec 07; 5(17795).
<http://www.nature.com/articles/srep17795>
2. Kumaran D, Adler M, Levit M, Krebs M, Sweeney R, and Swaminathan S. Interactions of a potent cyclic peptide inhibitor with the light chain of botulinum neurotoxin A: Insights from X-ray crystallography. *Bioorganic & Medicinal Chemistry.* 2015 Nov 15; 22(23):7264-7273.
<http://www.sciencedirect.com/science/article/pii/S0968089615301024>
3. Teng YG, Berger WT, Nesbitt NM, Kumar K, Baliaus TE, Rizzo RC, Tonge PJ, Ojima I, Swaminathan S. Computer-aided identification, synthesis, and biological evaluation of novel inhibitors for botulinum neurotoxin serotype A. *Bioorganic & Medicinal Chemistry.* 2015 Sep 01; 23(17):5489-5495.
<http://www.sciencedirect.com/science/article/pii/S0968089615006240>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The overall objective of the work is to develop countermeasures for biowarfare agents. The specific aims of the projects are to determine the three-dimensional structures of the agents. The purified agents are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Source (also located at Brookhaven National Laboratory) for x-ray diffraction studies. These results can lead to vaccine development, treatment, and/or diagnosis and detection. Additional information is available at

<https://www.bnl.gov/biosciences/>

Microorganisms and/or Toxins Studied: HHS Select Toxin.

Outdoor Studies: None.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Lawrence Livermore National Laboratory (LLNL)

2. Where is it located (provide both address and geographical location)?

7000 East Avenue, Livermore, California 94550 (62 km east-southeast of San Francisco, California)

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	1,685 m ²
BSL-3:	59.5 m ²
BSL-4:	0 m ²
Total laboratory floor area:	1,744.5 m ²

4. The organizational structure of each facility:

(i) Total number of personnel: 65

(ii) Division of personnel: Military: 0
Civilian: 65

(iii) **Division of personnel by category:**

Scientists	26
Engineers	11
Technicians	15
Administrative and support staff	13

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Biomedical Engineering, Biomedical Science, Biotechnology, Computational Biology, Computer Science, Environmental Science, Epidemiology, Genomics, Immunology, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Proteomics, Toxinology, Virology.

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense-partially

Department of Energy

Department of Health & Human Services (HHS)

Department of Homeland Security

(vii) **What are the funding levels for the following program areas:**

Research	\$ 4,474,000
Development	\$ 3,189,000
Test and evaluation	\$ 1,718,000
Total	\$ 9,381,000

(viii) Briefly describe the publication policy of the facility:

As a DOE/NNSA facility, LLNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LLNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LLNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Jaing C., Thissen J.B., Gardner S., McLoughlin K., Slezak T., Bossart G.D., Fair P.A. Pathogen Surveillance in Wild Bottlenose Dolphins (*Tursiops truncatus*). *Diseases of Aquatic Organisms*. 2015; 116(2):83-91. DOI: 10.3354/dao02917. <http://www.ncbi.nlm.nih.gov/pubmed/26480911>
2. Jaing CJ, Thissen JB, Gardner SN, McLoughlin KS, Hullinger PJ, Monday NA, Niederwerder MC, Rowland RRR. Application of a pathogen microarray for the analysis of viruses and bacteria in clinical diagnostic samples from pigs. *J Vet Diagn Invest*, 2015; 27(3): 313-325. DOI: 10.1177/1040638715578484. <http://www.ncbi.nlm.nih.gov/pubmed/25855363>
3. C. J. Doona, F. E. Feeherry, K. Kustin, G. G. Olinger, P. Setlow, A. J. Malkin, T. Leighton (2015). Fighting Ebola through novel decontamination technologies for the military. *Frontiers in Microbiology*. 2015; 6(663). doi: 10.3389/fmicb.2015.00663. <http://www.ncbi.nlm.nih.gov/pubmed/26322021>
4. Pinsky BA, Sahoo MK, Sandlund J, Kleman M, Kulkarni M, Grufman P, Nygren M, Kwiatkowski R, Baron EJ, Tenover F, Denison B, Higuchi R, Van Atta R, Beer NR, Carrillo AC, Naraghi-Arani P6, Mire CE, Ranadheera C, Grolla A, Lagerqvist N, Persing DH. Analytical Performance Characteristics of the Cepheid GeneXpert Ebola Assay for the Detection of Ebola Virus. *PLoS One*. 2015 Nov 12; 10(11):e0142216. doi: 10.1371/journal.pone.0142216. <http://www.ncbi.nlm.nih.gov/pubmed/26562786>
5. Sutton M, Kane SR, Wppard JR. Methyl Iodide Fumigation of *Bacillus anthracis* Spores. *J Environ Health*. 2015 Sep; 78(2):14-9. PMID: 26443693 <http://www.ncbi.nlm.nih.gov/pubmed/26502561>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, assay development for monitoring for biological decontamination/response, and bioforensics. Development of diagnostic platforms that use a variety of techniques, such as PCR, immunoassay, microarray, mass spectrometry and genomic sequencing to gather useful information about the species present in the sampling environment. Development of microbial forensic assays to help determine geographic origin and attribution. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions. Additional information is available at <https://missions.llnl.gov/biosecurity>.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens, simulants.

Outdoor Studies: There were no outdoor studies.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Los Alamos National Laboratory (LANL)

2. Where is it located (provide both address and geographical location)?

Bikini Atoll Road SM-30, Los Alamos, NM 87545

(Approximately 45 miles west of Santa Fe, New Mexico)

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	320 m ²
BSL-3:	0 m ²
BSL-4:	0 m ²
Total laboratory floor area:	320 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 47

(ii) **Division of personnel:**

Military	0
Civilian	47

(iii) **Division of personnel by category:**

Scientists	22
Engineers	1
Technicians	21
Administrative and support staff	3

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Bacteriology, Biological Science, Chemistry, Cell Biology, Microbiology, Molecular Biology, Bioinformatics, Genomics, Environmental Science, Plant Pathology, Analytical Biochemistry, Molecular Diagnostics, Public Health, Biotechnology, Biochemistry, Genetics, Virology.

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

Yes, 1.

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense (DoD) – partly
Department of Health & Human Services (HHS)
Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
U.S. Agency for International Development (USAID)

(vii) **What are the funding levels for the following program areas:**

Research	\$9,642,000
Development	\$ 1,900,000
Test and evaluation	\$ 1,300,000
Total	\$12,842,000

(viii) Briefly describe the publication policy of the facility:

As a DOE/NNSA facility, LANL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LANL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. LANL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Adams PG, Lamoureux L, Swingle KL, Mukundan H, Montaño GA. Biochemical lithography: Patterning of supported lipid bilayers with membrane amphiphiles. *Nature Scientific Reports*, *Nature Scientific Reports*, 5, Article number: 10331 (2015) doi:10.1038/srep10331. 6. [http://www.cell.com/biophysj/abstract/S0006-3495\(14\)03873-9](http://www.cell.com/biophysj/abstract/S0006-3495(14)03873-9)
2. Adams PG, Lamoureux L, Swingle KL, Mukundan H, Montaño GA. Lipopolysaccharide-induced dynamic lipid membrane reorganization: tubules, perforations, and stacks., *Biophys J*. 2014 Jun 3;106(11):2395-407. <http://www.ncbi.nlm.nih.gov/pubmed/24896118>
3. Anderson AS, Mukundan H, McInroy R and Clegg SM, Combined LIBS-Raman for remote detection and characterization of biological samples, *Proc. SPIE 9328, Imaging, Manipulation, and Analysis of Biomolecules, Cells, and Tissues XIII*, 932811 (March 2, 2015); doi:10.1117/12.2076832. 9. <http://proceedings.spiedigitallibrary.org/proceeding.aspx?articleid=2194760>
4. Chapman, C., M. Henry, K. A. Bishop-Lilly, J. Awosika, A. Briska, R. N. Ptashkin, T. Wagner, C. Rajanna, H. Tsang, S. L. Johnson, V. P. Mokashi, P. S. G. Chain and S. Sozhamannan (2015). Scanning the Landscape of Genome Architecture of Non-O1 and Non-O139 *Vibrio cholerae* by Whole Genome Mapping Reveals Extensive Population Genetic Diversity. *PLoS ONE* 10(d): e0120311. Doi:10.1371/journal.pone.0120311 <http://www.ncbi.nlm.nih.gov/pubmed/25794000>
5. Cui HH, TH Erkkila, PS Chain, and M Vuyisich (2015). Building International Genomics Collaboration for Global Health Security. *Frontiers in Public Health* 3. Doi: 10.3389/fpubh.2015.00264. <http://journal.frontiersin.org/article/10.3389/fpubh.2015.00264/full>.
6. Dichosa AEK, KW Davenport, P-E Li, SA Ahmed, H Daligault, CD Gleasner, Y Kunde, K McMurry, C C Lo, KG Reitenga, AR Daughton, X Shen, S Fretze, D Wang, SL Johnson, DI Drautz-Moses, S Schuster, PS Chain, C Han. Draft genome sequence of *Thauera* sp. SWB20 isolated from a Singapore wastewater facility using gel microdroplets. *Genome Announcements*. 3(2): e00132-15. doi: 10.1128/genomeA.00132-15, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4395064/>
7. Hong-Geller, E. and Micheva-Viteva, S. (2015) Targeting bacterial persistence to develop therapeutics against infectious disease in Drug Discovery and Development – From Molecules to Medicine, ISBN 978-953-51-2128-2 <http://www.intechopen.com/books/drug-discovery-and-development-from-molecules-to-medicine/targeting-bacterial-persistence-to-develop-therapeutics-against-infectious-disease>
8. Johnson, S. L., A. Khiani, K. A. Bishop-Lilly, C. Chapman, M. Patel, K. Verratti, H. Teshima, A. C. Munk, D. C. Bruce, C. S. Han, G. Xie, K. W. Davenport, P. Chain and S. Sozhamannan (2015). Complete Genome Assemblies for Two Single-Chromosome *Vibrio cholerae* Isolates, Strains 1154-74 (Serogroup O49) and 10432-62 (Serogroup O27). *Genome Announcements* 3(3). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4432340/>

9. Johnson, S. L., A. L. Baker, P. S. Chain, B. J. Currie, H. E. Daligault, K. W. Davenport, C. B. Davis, T. J. J. Inglis, M. Kaestli, S. Koren, M. Mayo, A. J. Merritt, E. P. Price, D. S. Sarovich, J. Warner and M. J. Rosovitz (2015). Whole-Genome Sequences of 80 Environmental and Clinical Isolates of *Burkholderia pseudomallei*. *Genome Announcements* 3(1). <http://genomea.asm.org/content/3/1/e01282-14.full>
10. Johnson, S. L., H. E. Daligault, K. W. Davenport, J. Jaissle, K. G. Frey, J. T. Ladner, S. M. Broomall, K. A. Bishop-Lilly, D. C. Bruce and S. R. Coyne (2015). Thirty-two complete genome assemblies of nine *Yersinia* species, including *Y. pestis*, *Y. pseudotuberculosis*, and *Y. enterocolitica*. *Genome announcements* 3(2): e00148-00115. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417686/>
11. Johnson, S. L., H. E. Daligault, K. W. Davenport, J. Jaissle, K. G. Frey, J. T. Ladner, S. M. Broomall, K. A. Bishop-Lilly, D. C. Bruce and H. S. Gibbons (2015). Complete genome sequences for 35 biothreat assay-relevant *Bacillus* species. *Genome announcements* 3(2): e00151-00115. <http://www.ncbi.nlm.nih.gov/pubmed/25931591>
12. Johnson, S. L., H. E. Daligault, K. W. Davenport, S. R. Coyne, K. G. Frey, G. I. Koroleva, S. M. Broomall, K. A. Bishop-Lilly, D. C. Bruce and O. Chertkov (2015). Genome sequencing of 18 *Francisella* strains to aid in assay development and testing. *Genome announcements* 3(2): e00147-00115. <http://www.ncbi.nlm.nih.gov/pubmed/25931589>
13. Johnson, S. L., K. A. Bishop-Lilly, J. T. Ladner, H. E. Daligault, K. W. Davenport, J. Jaissle, K. G. Frey, G. I. Koroleva, D. C. Bruce and S. R. Coyne (2015). Complete genome sequences for 59 *Burkholderia* isolates, both pathogenic and near neighbor. *Genome Announcements* 3(2): e00159-00115. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4417688/>
14. Johnson, S. L., T. D. Minogue, H. E. Daligault, M. J. Wolcott, H. Teshima, S. R. Coyne, K. W. Davenport, J. G. Jaissle and P. S. Chain (2015). Finished Genome Assembly of Warm Spring Isolate *Francisella novicida* DPG 3A-IS. *Genome Announcements* 3(5). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574370/>
15. Johnson, S. L., T. D. Minogue, H. E. Daligault, M. J. Wolcott, H. Teshima, S. R. Coyne, K. W. Davenport, J. G. Jaissle and P. S. Chain (2015). Finished Genome Assembly of *Yersinia pestis* EV76D and KIM 10v. *Genome Announcements* 3(5). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4574367/>
16. Johnson, S. L., T. D. Minogue, H. Teshima, K. W. Davenport, A. A. Shea, H. L. Miner, M. J. Wolcott and P. S. G. Chain (2015). Finished Genome Sequence of *Bacillus cereus* Strain 03BB87, a Clinical Isolate with *B. anthracis* Virulence Genes. *Genome Announcements* 3(1). <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4299909/>
17. Johnson, S., A. Khiani, K. Bishop-Lilly, C. Chapman, M. Patel, K. Verratti, H. Teshima, A. Munk, D. Bruce and C. Han (2015). Complete genome assemblies for two single-chromosome *Vibrio cholerae* isolates, strains 1154-74 (serogroup O49) and 10432-62 (serogroup O27). *Genome Announcements* 3(3): e00462-00415. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4432340/>
18. Lamoureux L, Adams P, Banisadr A, Stromberg ZR, Graves S, Montano G, Moxley RM and Mukundan H. An optical biosensor for detection of pathogen biomarkers from Shiga toxin-producing *Escherichia coli* in ground beef samples Proc. SPIE 9310, Frontiers in Biological Detection: From Nanosensors to Systems VII, 931004 (2 March 2015); doi: 10.1117/12.2079658 <http://proceedings.spiedigitallibrary.org/proceeding.aspx?articleid=2194158>
19. Smith, T. J., K. K. Hill, G. Xie, B. T. Foley, C. H. D. Williamson, J. T. Foster, S. L. Johnson, O. Chertkov, H. Teshima, H. S. Gibbons, L. A. McNew, M. A. Karavis and L. A. Smith (2015). Genomic sequences of six botulinum neurotoxin-producing strains representing three clostridial species illustrate the mobility and diversity of botulinum neurotoxin genes. *Infection, Genetics and Evolution* 30: 102-113. <http://www.ncbi.nlm.nih.gov/pubmed/25489752>
20. Stromberg LR, Stromberg ZE, Banisadr A, Graves SW, Moxley RA and Mukundan H, Purification and characterization of lipopolysaccharides from six strains of non-O157 Shiga toxin-producing *Escherichia coli*. *Journal of Microbiological Methods*, 116, 1-7, 2015. Presentations: several presentations, video recordings, radio and television interviews and slides are also available on line. <http://www.ncbi.nlm.nih.gov/pubmed/26093258>

21. Tuberculosis, Leprosy and Mycobacterial Diseases of Man and Animals, Edited by Harshini Mukundan, Ray Waters, Mark Chambers and Michelle Larsen, CABI Press, Published October 2015. 5.
<http://www.amazon.com/Tuberculosis-Leprosy-Mycobacterial-Diseases-Animals/dp/1780643969>
22. Zhgenti, E., S. L. Johnson, K. W. Davenport, G. Chanturia, H. E. Daligault, P. S. Chain and M. P. Nikolich (2015). Genome Assemblies for 11 *Yersinia pestis* Strains Isolated in the Caucasus Region. *Genome Announcements* 3(5). <http://genomea.asm.org/content/3/5/e01030-15.long>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection, integrative biosurveillance and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interaction; study molecular, chemical, and physical characteristics of biothreat agents, including bacteria, viruses and toxins, for detection, characterization, assay design and improvement; evaluate detection assay and platform performance; assess commercial techniques for pathogen detection and biosurveillance on environmental monitoring procedures; develop DNA, RNA and protein based bioforensics assays; develop next generation high throughput microbial sequencing, finishing and analysis capabilities; perform viral and bacterial pathogen sequencing for characterization, comparative genomic analysis, and metagenomic analysis; develop high throughput assays for host-pathogen protein interactions screening; develop and validate assays to improve the ability to identify and characterize bioterrorism incident; and identify host molecular targets as potential therapeutic candidates. Additional information is available at <http://www.lanl.gov/science-innovation/capabilities/bioscience-biosecurity-health/biosecurity-health/index.php>.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A

Outdoor Studies: There were no outdoor studies.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?

Pacific Northwest National Laboratory (PNNL)

2. Where is it located (provide both address and geographical location)?

902 Battelle Boulevard, Richland, Washington 99352 (The Pacific Northwest National Laboratory is located in north Richland, Washington, and is served by the Tri-Cities Airport in Pasco. Richland, Pasco and Kennewick make up the Tri-Cities where the Columbia, Snake and Yakima Rivers meet before heading to the Pacific Ocean.)

3. Floor area of laboratory areas by containment level (m²):

Richland campus:	BSL-2	769 m ²
	BSL-3	0 m ²
	BSL-4	0 m ²
	Total laboratory floor area:	769 m ²

Sequim campus:	BSL-2	81 m ²
	BSL-3	0 m ²
	BSL-4	0 m ²
	Total laboratory floor area	81 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 94

(ii) **Division of personnel:**

Military	0
Civilian	94

(iii) **Division of personnel by category:**

Scientists	80
Engineers	2
Technicians	0
Admin and Support Staff	12

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science, Cell Biology, Chemistry, Computational Biology, Genetics, Genomics, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Pathology, Proteomics, Structural Biology, Systems Biology, Virology.

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
Yes, 1.

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense (DoD)-partially

Department of Energy (DOE)

Department of Health & Human Services (HHS)

Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
Other Government Agencies

(vii) What are the funding levels for the following program areas:

Research	\$10,483,000
Development	\$314,000
Test and evaluation	\$1,391,000
Total	\$12,188,000

(viii) Briefly describe the publication policy of the facility:

As a DOE Office of Science facility, PNNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. PNNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. PNNL also has procedures in place to manage and protect classified, controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [US Department of Energy, Scientific and Technical Information Management: <https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>] For this location, a searchable database of materials published since 1988 is available at <http://www.pnnl.gov/publications/>.

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Powell JD, BM Hess, JR Hutchison, and TM Straub. Construction of an in vitro primary lung co-culture platform derived from New Zealand white rabbits. *In Vitro Cellular & Developmental Biology - Animal*. 2015 May 10; 51(5):433-440. doi:10.1007/s11626-014-9853-z.
<http://www.ncbi.nlm.nih.gov/pubmed/25491427>
2. Powell JD, JR Hutchison, BM Hess, and TM Straub. *Bacillus anthracis* spores germinate extracellularly at air-liquid interface in an in vitro lung model under serum-free conditions. *Journal of Applied Microbiology*. 2015 September 1; 119(3):711-723. doi:10.1111/jam.12872.
<http://onlinelibrary.wiley.com/doi/10.1111/jam.12872/full>
3. Guo CJ, WW Sun, KS Bruno, BR Oakley, NP Keller, and CC Wang. Spatial regulation of a common precursor from two distinct genes generates metabolite diversity. *Chemical Science*. 2015 July 13; Vol 6 pages 5913- 5921 DOI: 10.1039/c5sc01058f.
<http://pubs.rsc.org/en/content/articlehtml/2015/sc/c5sc01058f>
4. Baker SE, W Schackwitz, lipzen, JX Martin, S Haridas, KM LaButti, IV Grigoriev, BA Simmons, and K McCluskey. Draft Genome Sequence of *Neurospora crassa* Strain FGSC 73. *Genome Announcements*. 2015 April 2. Vol 3 issue 2 doi:10.1128/genomeA.00074-15. <http://genomea.asm.org/content/3/2/e00074-15.full.pdf+html>
5. Powell JD. From Pandemic Preparedness to Biofuel Production: Tobacco Finds Its Biotechnology Niche in North America. *Agriculture*. 2015 September 25; 5(4):901-917. doi:10.3390/agriculture5040901.
<http://www.mdpi.com/2077-0472/5/4/901>

6. Baugh L, I Phan, DW Begley, MC Clifton, B Armour, DM Dranow, BM Taylor, MM Muruthi, J Abendroth, JW Fairman, D Fox III, SH Dieterich, BL Staker, AS Gardberg, R Choi, SN Hewitt, AJ Napuli, J Myers, L Barrett, Y Zhang, M Ferrell, E Mundt, K Thompkins, N Tran, S Lyons-Abbott, A Abramov, A Sekar, D Serbzhinskiy, D Lorimer, GW Buchko, R Stacy, LJ Stewart, TE Edwards, WC Van Voorhis, and PJ Myler. 2015. Increasing the Structural Coverage of Tuberculosis Drug Targets. *Tuberculosis*. 2015 March 13; 95(2):142-148. doi:10.1016/j.tube.2014.12.003.
<http://www.ncbi.nlm.nih.gov/pubmed/25613812>
7. Buchko GW, TE Edwards, SN Hewitt, I Phan, WC Van Voorhis, SI Miller, and PJ Myler. Backbone chemical shift assignments for the sensor domain of the *Burkholderia pseudomallei* histidine kinase RisS: - "missing" resonances at the dimer interface. *Biomolecular NMR Assignments*. 2015 September 17; 9(2):381-385. doi:10.1007/s12104-015-9614-2. <http://www.ncbi.nlm.nih.gov/pubmed/25957069>
8. Buchko GW, A Yee, A Semesi, PJ Myler, CH Arrowsmith, and R Hui. Solution-state NMR structure of the putative morphogene protein BOLA (PFE0790c) from *Plasmodium falciparum*. *Acta Crystallographica. Section F*. 2015 April 18; F71(5):514-521. doi: 10.1107/S2053230X1402799X.
<http://www.ncbi.nlm.nih.gov/pubmed/25945703>
9. Buchko GW, J Abendroth, MC Clifton, H Robinson, Y Zhang, SN Hewitt, BL Staker, TE Edwards, WC Van Voorhis, and PJ Myler. Structure of a CutA1 divalent-cation tolerance protein from *Cryptosporidium parvum*, the protozoal parasite responsible for cryptosporidiosis. *Acta Crystallographica. Section F*. 2015 April 27; F71(5):522-530. doi:10.1107/S2053230X14028210.
<http://www.ncbi.nlm.nih.gov/pubmed/25945704>
10. Buchko GW, A Perkins, D Parsonage, LB Poole, and PA Karplus. Backbone chemical shift assignments for *Xanthomonas campestris* peroxiredoxin Q in the reduced and oxidized states: a dramatic change in backbone dynamics. *Biomolecular NMR Assignments*. 2015 October; doi:10.1007/s12104-015-9637-8.
<http://www.ncbi.nlm.nih.gov/pubmed/26438558>
11. Staker BL, GW Buchko, and PJ Myler. Recent contributions of structure-based drug design to the development of antibacterial compounds. *Current Opinion in Microbiology*. 2015 October 12; 27(1):133-138. doi:10.1016/j.mib.2015.09.003. <http://www.ncbi.nlm.nih.gov/pubmed/26458180>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: PNNL is involved in biodefense-related activities, such as agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of detection methods (e.g., nucleic acid, toxin, and proteomic signatures), testing and evaluation of commercial off the shelf equipment for agent detection as well as investigation of next generation biodetection equipment, biological and chemical forensics, investigation of natural history of agents, pathogenesis studies, and interrogating DNA sequencing data and related analysis tools. No outdoor studies of biological aerosols were collected. Additional information is available at http://www.pnnl.gov/nationalsecurity/technical/cbps/chem_biological_science.stm.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap), NIAID Category A, Simulants

Outdoor Studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes: Facilities

1. Name of the facility:

Sandia National Laboratories (SNL)

2. Where is it located?

New Mexico Campus: P. O. Box 5800, Albuquerque, NM 87185 (located on Kirtland Air Force Base, in southeastern Albuquerque)

California Campus: 7011 East Avenue, Livermore, California (located in Livermore, CA.)

(Note: Personnel and budget are shared between New Mexico and California campuses.)

3. Floor area of laboratory areas by containment level (m²):

New Mexico campus: BSL-2: 652.58 m²
 BSL-3: 0 m²
 BSL-4: 0 m²
 Total laboratory floor area: 652.58 m²

4. Organizational structure of each facility:

(i) **Total number of personnel:** New Mexico campus: 157
California campus: 43

(ii) **Division of personnel:** **Military** 0
Civilian 200

(iii) Division of personnel by category:	Scientists	113
	Engineers	29
	Technicians	48
	Admin and Support Staff	10

(iv) Scientific discipline(s) that best describes field of work:

Aerosol Science, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Materials Science, Medicine, Nanotechnology, Aerobiology, Bioinformatics, Biological Science, Cell Biology, Immunology, Molecular Biology, Virology, Molecular Diagnostics, Biophysics, Chemistry, Physics, Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Bacteriology, Bioinorganic Chemistry, Biomedical Science, Computational Biology, Computer Engineering, Computer Science, Electrical Engineering, Environmental Engineering, Environmental Science, Genetics, Genomics, Mass Spectrometry, Mathematics, Mechanical Engineering, Microbial Forensics, Microbiology, Neuroscience, Operations Research Analysis, Optical Spectroscopy, Pathology, Physiology, Polymer Science, Protein Engineering, Proteomics, Structural Biology, Toxicology

(v) Are Contractor staff working in the facility?

Yes Number: 10 (9 New Mexico campus; 1 California campus)

(vi) What is (are) the source(s) of funding for the work conducted in the facility?

- Department of Defense (DoD)
- Department of Health and Human Services (HHS)
- Department of Homeland Security (DHS)
- Internal (Laboratory Directed Research & Development, LDRD)
- Private sector

(vii) What are the funding levels for Research and Development and Testing and Evaluation as of the most recent calendar year?

Research	\$ 12,543,979.28
Development	\$ 2,738,717.75
Test and Evaluation	\$ 796,106.75
Total	\$ 16,078,803.78

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Sandia National Laboratories is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. SNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. SNL also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. [Department of Energy, Scientific and Technical Information Management:

<https://www.directives.doe.gov/directives/0241.1-BOrder-b/view>]

(ix) Provide a list of publicly available papers and reports resulting from work during the previous 12 months (To include authors, titles, and full references.):

1. Baca JT, Severns V, Lovato D, Branch DW, Larson RS. Rapid detection of Ebola virus with a reagent-free, point-of-care biosensor. Sensors (Switzerland). 2015;15(4):8605-14. <http://www.mdpi.com/1424-8220/15/4/8605.htm>
2. Bent ZW, Poorey K, Brazel DM, LaBauve AE, Sinha A, Curtis DJ, House SE, Tew KE, Hamblin RY, Williams KP, Branda SS, Young GM, Meagher RJ. Transcriptomic Analysis of Yersinia enterocolitica Biovar 1B Infecting Murine Macrophages Reveals New Mechanisms of Extracellular and Intracellular Survival. Infect Immun. 2015;83(7):2672-85. <http://iai.asm.org/content/83/7/2672.long>
3. Cui F, Rhee M, Singh A, Tripathi A. Microfluidic Sample Preparation for Medical Diagnostics. Annu Rev Biomed Engineering. 2015;17:267-86. http://www.annualreviews.org/doi/full/10.1146/annurev-bioeng-071114-040538?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&
4. Harper JC, Carson BD, Bachand GD, Arndt WD, Finley MR, Brinker CJ, Edwards TL. Laser Machined Plastic Laminates: Towards Portable Diagnostic Devices for Use in Low Resource Environments. Electroanalysis. 2015;27(11):2503-12. <http://onlinelibrary.wiley.com/doi/10.1002/elan.201500359/full>
5. Hill SC, Williamson CC, Doughty DC, Pan Y-L, Santarpia JL, Hill HH. Size-dependent fluorescence of bioaerosols: Mathematical model using fluorescing and absorbing molecules in bacteria. Journal of Quantitative Spectroscopy and Radiative Transfer. 2015;157:54-70.

6. Johnson PE, Muttil P, MacKenzie D, Carnes EC, Pelowitz J, Mara NA, Mook WM, Jett SD, Dunphy DR, Timmins GS, Brinker CJ. Spray-Dried Multiscale Nano-biocomposites Containing Living Cells. *ACS Nano*. 2015;9(7):6961-77. <http://pubs.acs.org/doi/abs/10.1021/acsnano.5b01139>
7. Koh CY, Schaff UY, Piccini ME, Stanker LH, Cheng LW, Ravichandran E, Singh BR, Sommer GJ, Singh AK. Centrifugal microfluidic platform for ultrasensitive detection of botulinum toxin. *Anal Chem*. 2015;87(2):922-8. <http://pubs.acs.org/doi/10.1021/ac504054u>
8. Ratnesar-Shumate S, Pan Y-L, Hill SC, Kinahan S, Corson E, Eshbaugh J, Santarpia JL. Fluorescence spectra and biological activity of aerosolized bacillus spores and MS2 bacteriophage exposed to ozone at different relative humidities in a rotating drum. *J Quant Spectrosc Radiat Transfer*. 2015;153:13-28. <http://www.sciencedirect.com/science/article/pii/S002240731400418X>
9. Rogers DM, Kent MS, Rempe SB. Molecular basis of endosomal-membrane association for the dengue virus envelope protein. *Biochimica et Biophysica Acta (BBA) - Biomembranes*. 2015;1848(4):1041-52. <http://www.sciencedirect.com/science/article/pii/S0005273614004544>
10. Vanegas JM, Rogers DM, Kent MS, Rempe SB. Role of Electrostatic Interactions in the Anchoring of Dengue E Protein to Lipid Membranes. *Biophys J*. 2015;108(2, Supplement 1):406a. [http://www.cell.com/biophysj/abstract/S0006-3495\(14\)03438-9](http://www.cell.com/biophysj/abstract/S0006-3495(14)03438-9)

5. Briefly describe the biological defense work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: To improve our nation's ability to anticipate and defend against biological threats, our multidisciplinary research team is applying Sandia's traditional strengths in engineering and technology development to achieve the following goals: 1) Gain basic knowledge regarding the fundamental molecular processes of pathogenesis, including the dynamic interactions between microbial pathogens and their hosts; 2) Develop assays, novel materials, and platforms to detect and diagnose traditional and unknown pathogens, as well as to discover novel therapeutic targets; and 3) Obtain an understanding of the microbiome's effects on human health in the absence or in the presence of an infectious disease. Additional information is available at http://www.sandia.gov/research/research_foundations/bioscience/index.html.

Microorganisms and/or toxins studied: No select agents, select toxins or NIAID Category A pathogens were studied at the facility.

Outdoor studies: There were no outdoor studies.

National biological defence research and development programmes**1. What is the name of the facility?**

Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Laboratory Services (DLS)

2. Where is it located (include both address and geographical location)?

4770 Buford Highway, Atlanta, Georgia 30341

3. Floor area of laboratory areas by containment level:

BL2	568 m ²
BL3	0 m ²
BL4	0m ²
Total laboratory floor area	568 m ²

4. The organizational structure of each facility.

(i) Total number of personnel 21

(ii) Division of personnel:

Military	0
Civilian	21

(iii) Division of personnel by category:

Scientists	21
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Biochemistry, Biology, Chemistry, Mass Spectrometry, Proteomics

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Contractor staff = 6

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	\$1,302,354
Development	\$363,375
Test and evaluation	\$742,086
Total	\$2,407,816

(viii) Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings. The clearance policy for information products disseminated outside CDC for public use is available online at:

<http://www.cdc.gov/od/science/policies> CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: <http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf>

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Kalb SR, Baudys J, Barr JR. Detection of the HA-33 Protein in Botulinum Neurotoxin Type G Complex by Mass Spectrometry. *BMC Biochemistry*. 2015;Oct23;15(1):227.
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4619279/pdf/12866_2015_Article_567.pdf
2. Kalb SR, Boyer AE, Barr JR. Mass Spectrometric Detection of Bacterial Protein Toxins and their Enzymatic Activity. *Toxins*. 2015 Aug 31; 7(9): 3497-511. <http://www.mdpi.com/2072-6651/7/9/3497>
3. Kalb SR, Schieltz DM, Becher F, Astot C, Fredriksson SA, Barr JR. Recommended mass spectrometry-based strategies to identify ricin-containing samples. *Toxins*. 2015 Dec; 7(12): 4881-4894.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4690104/>
4. Kalb SR, Baudys J, Wang D, Barr JR. Recommended mass spectrometry-based strategies to identify botulinum neurotoxin-containing samples. *Toxins*. 2015, May 19; 7(5): 1765-1778.
<http://www.mdpi.com/2072-6651/7/5/1765>
5. Wang D., Krilich JC, Baudys J, Barr JR, Kalb SR. Enhanced detection of type C botulinum neurotoxin by the Endopep-MS assay through optimization of peptide substrates. *Bioorganic and Medicinal Chemistry*. 2015 Jul 1; 23(13): 3667-73.
<http://www.sciencedirect.com/science/article/pii/S0968089615003090>
6. Kalb SR, Baudys J, Raphael BH, Dykes JK, Luquez C, Maslanka SE, Barr JB. Functional Characterization of Botulinum Neurotoxin Serotype H as a Hybrid of Known Serotypes F and A (BoNT F/A). *Analytical Chemistry*. 2015 Apr 7; 87(7): 3911-3917.
<http://pubs.acs.org/doi/abs/10.1021/ac504716v>
7. Kull S, Schultz KM, Weisemann J, Kirchner S, Schreiber T, Bollenbach A, Dabrowski PW, Nitsche A, Kalb SR, Dorner MB, Barr JR, Rummel A, Dorner BG. Isolation and Functional Characterization of the Novel Clostridium botulinum Neurotoxin A8 Subtype. *PLoS One*, 2015, Feb 6; 10(2): e0116381.
<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0116381>
8. Kalb SR, Krilich JC, Dykes JK, Luquez C, Maslanka SE, J.R. Barr JR. Endopep-MS for the Detection of Botulinum Toxins A, B, E, and F in Foods. *Journal of Agricultural and Food Chemistry*. 2015 Jan 22.
<http://pubs.acs.org/doi/abs/10.1021/jf505482b>
9. Pantazides BG, Crow BS, Garton JW, Quiñones-González J, Blake TA, Thomas JD, Johnson RC. Simplified Method for Quantifying Sulfur Mustard Adducts to Blood Proteins by Ultrahigh Pressure Liquid Chromatography-Isotope Dilution Tandem Mass Spectrometry. *Chemical Research in Toxicology*. 2015; 28 (2): 256-261. DOI: 10.1021/tx500468h; PMID: 25622494
<http://www.ncbi.nlm.nih.gov/pubmed/25622494>
10. Darryl Johnson, Melissa D. Carter, Brian S. Crow, Samantha L. Isenberg, Leigh Ann Graham, H. Akin Erol, Caroline M. Watson, Brooke G. Pantazides, Marcel J. van der Schans, Jan P. Langenberg, Daan Noort, Thomas A. Blake, Jerry D. Thomas, Rudolph C. Johnson. "Quantitation of ortho-cresyl phosphate adducts to butyrylcholinesterase in human serum by immunomagnetic-UHPLC-MS/MS." *Journal of Mass Spectrometry*. 2015, 50 (4), 683–692. DOI 10.1002/jms.3576; PMID: 26149113
<http://onlinelibrary.wiley.com/doi/10.1002/jms.3576/abstract>
11. William A. Bragg, Sharon W. Lemire, Rebecca M. Coleman, Elizabeth I. Hamelin, Rudolph C. Johnson. "Detection of human exposure to saxitoxin and neosaxitoxin in urine by online-solid phase extraction-liquid chromatography-tandem mass spectrometry." *Toxicon*. 2015, 99, 118-124. DOI: 10.1016/j.toxicon.2015.03.017; PMID: 25817003
<http://www.sciencedirect.com/science/article/pii/S0041010115000859>
12. Jonas W. Perez, Brooke G. Pantazides, Caroline M. Watson, Jerry D. Thomas, Thomas A. Blake, Rudolph C. Johnson. "Enhanced Stability of Blood Matrices Using a Dried Sample Spot Assay to Measure Human Butyrylcholinesterase Activity and Nerve Agent Adducts." *Analytical Chemistry*. 2015, 87 (11), 5723-5729. DOI: 10.1021/acs.analchem.5b00893; PMID: 25955132

<http://pubs.acs.org/doi/abs/10.1021/acs.analchem.5b00893>

13. Isenberg SL, Carter MD, Graham LA, Mathews TP, Johnson D, Thomas JD, Pirkle JL, Johnson RC. Quantification of Metabolites for Assessing Human Exposure to Soapberry Toxins Hypoglycin A and Methylenecyclopropylglycine. *Chemical Research in Toxicology*. 2015; 28 (9): 1753-1759. DOI: 10.1021/acs.chemrestox.5b00205; PMID: 26328472
<http://pubs.acs.org/doi/abs/10.1021/acs.chemrestox.5b00205?journalCode=crtoec>

14. Peng H, Brimijoin S, Hrabovska A, Targosova K, Krejci E, Blake TA, Johnson CR, Masson P, Lockridge O. Comparison of 5 monoclonal antibodies for immunopurification of human butyrylcholinesterase on Dynabeads: KD values, binding pairs, and amino acid sequences. *Chemico-Biological Interactions*. 2015; 240: 336-345. DOI: 10.1016/j.cbi.2015.08.024; PMID: 26343001
<http://www.ncbi.nlm.nih.gov/pubmed/26343001>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Division of Laboratory Sciences develops methods for measuring selected toxins to help improve detection and diagnosis during a public health response to biological toxins. More information can be found at <http://www.cdc.gov/nceh/dls/>.

Agents Microorganisms and/or toxins studied: HHS Select Toxins

Outdoor studies: Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.

National biological defence research and development programmes

1. What is the name of the facility?

Centers for Disease Control and Prevention (CDC), Office of Infectious Diseases (OID)

2. Where is it located (provide both address and geographical location)?

1600 Clifton Road N.E., Atlanta, Georgia 30333

3. Floor area of laboratory areas by containment level:

BL2	294 m ²
BL3	2143 m ²
BL4	543 m ²
Total laboratory floor area	2980 m ²

4. The organizational structure of each facility.

(i) Total number of personnel 236

(ii) Division of personnel: Military 3
Civilian 233

(iii) Division of personnel by category:

Scientists	199
Engineers	0
Technicians	23
Administrative and support staff	14

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Animal Science, Biochemistry, Bioinformatics, Biology, Biological Science, Cell Biology, Chemistry, Clinical Immunology, Ecology, Entomology, Epidemiology, Genetics, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Public Health, Statistics, Veterinary Medicine, Virology

v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Contractor staff = 59

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Agency for International Development (USAID)
Department of Defense (DOD)
Department of Health and Human Services (HHS)
Department of Homeland Security (DHS)
Department of State (DOS)

(vii) What are the funding levels for the following program areas:

Research	\$ \$13,833,850
Development	\$ \$7,633,607
Test and evaluation	\$ \$9,401,192
Total	\$ \$30,868,649

(viii) Briefly describe the publication policy of the facility:

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies>

CDC Policy on "Oversight and clearance of dual use research of concern" is available online at: <http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf>

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

1. Ackelsberg JA, Rakeman J, Hughes S, Petersen J, Mead P, Schriefer M, Kingry L, Hoffmaster A, Gee JE. Lack of Evidence for Plague or Anthrax on the New York City Subway. *Cell Systems*. 2015; 1(1):4-9. http://ac.els-cdn.com/S2405471215000162/1-s2.0-S2405471215000162-main.pdf?_tid=39584d9c-c68b-11e5-bdfe-00000aacb35d&acdnat=1454073877_d08987703406f437d3eeee63125bd9d9
2. Albarino CG, Wiggleton Guerrero L, Lo MK, Nichol ST, and Towner JS. Development of a reverse genetics system to generate a recombinant Ebola virus Makona expressing a green fluorescent protein. *Virology*. 2015; 484:259-64. <http://www.ncbi.nlm.nih.gov/pubmed/26122472>
3. Albarino CG, Wiggleton Guerrero L, Spengler JR, Uebelhoer LS, Chakrabarti AK, Nichol ST, Towner JS. Recombinant Marburg viruses containing mutations in the IID region of VP35 prevent inhibition of Host immune responses. *Virology*. 2015; 476:85-91. <http://www.ncbi.nlm.nih.gov/pubmed/25531184>
4. Amman BR, Albarino CG, Bird BH, Nyakaruhaka L, Sealy TK, Balinandi S, Schuh AJ, Campbell SM, Stroher U, Jones ME, Vodzack ME, Reeder DM, Kaboyo W, Nichol ST, and Towner JS. A Recently Discovered Pathogenic Paramyxovirus, Sosuga Virus, is Present in *Rousettus aegyptiacus* Fruit Bats at Multiple Locations in Uganda. *J Wild Dis*. 2015; 51(3):774-9. <http://www.ncbi.nlm.nih.gov/pubmed/25919464>
5. Amman BR, Jones ME, Sealy TK, Uebelhoer LS, Schuh AJ, Bird BH, Coleman-McCray JD, Martin B E, Nichol ST, and Towner JS. Oral shedding of Marburg virus in experimentally infected Egyptian fruit bats (*Rousettus aegyptiacus*). *J Wild Dis*. 2015; 51(1):113-24. <http://www.ncbi.nlm.nih.gov/pubmed/25375951>
6. Anderson AD, Szymanski TJ, Emery MP, Kohrs PH, Bjork AC, Marsden-Haug N, Nett RJ, Woodhall DM, Self JS, Fitzpatrick KA, Priestley RA, Kersh GJ. Epizootiological investigation of a Q fever outbreak and implications for future control strategies. *J Am Vet Med Assoc*. 2015 Dec 15; 247(12):1379-86. <http://www.ncbi.nlm.nih.gov/pubmed/26642131>
7. Benoit TJ, Blaney DD, Doker TJ, Gee JE, Elrod MG, Rolim DB, Inglis T.J.J., Hoffmaster AR, Bower WA, Walke HT. Review Article: A Review of Melioidosis Cases in the Americas. *AJTMH* 2015; 93(6):1134-1139. <http://www.ajtmh.org/content/early/2015/10/07/ajtmh.15-0405.full.pdf>
8. Benoit, TJ, Blaney DD, Gee JE, Elrod MG, Hoffmaster AR, Doker TJ, Bower WA, Walke HT. Melioidosis Cases and Selected Reports of Occupational Exposures to *Burkholderia pseudomallei* — United States, 2008–2013. *MMWR Surveill Summ*. 2015; 64(No. SS-5). <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6405a1.htm>
9. Bergeron E, Zivcec M, Chakrabarti AK, Nichol ST, Albarino CG, and Spiropoulou CF. Recovery of Recombinant Crimean Congo Hemorrhagic Fever Virus Reveals a Function for Non-structural Glycoproteins Cleavage by Furin. *PLoS Pathog*. 2015; 11(5):e1004879. <http://www.ncbi.nlm.nih.gov/pubmed/25933376>
10. Bird BH, Spengler JR, Chakrabarti AK, Khristova ML, Sealy TK, Coleman-McCray JD, Martin BE, Dodd KA, Goldsmith CS, Sanders J, Zaki SR, Nichol ST, and Spiropoulou CF. Humanized Mouse Model of Ebola Virus Disease Mimics the Immune Responses in Human Disease. *J Infect Dis*. 2015 Nov 17. [Epub ahead of print] <http://www.ncbi.nlm.nih.gov/pubmed/26582961>
11. Bower, H., Grass, J.E., Veltus, E., Brault, A., Campbell, S., Basile, A.J., Wang, D., Paddock, C.D., Erickson, B.R., Salzer, J.S., Belser, J., Chege, E., Seneca, D., Saffa, G., Stroher, U., Decroo, T. and Caleo, G.M. Delivery of an Ebola Virus-Positive Stillborn Infant in a Rural Community Health Center, Sierra Leone, January 2015. *Am J Trop Med Hyg*. 2016 Feb 3; 94(2): 417-9. Published online November 10, 2015, doi: 10.4269/ajtmh.15-0619

<http://www.ncbi.nlm.nih.gov/pubmed/26556830>

12. Bugrysheva, J.V., Sue, D., Hakovirta, J., Loparev, V.N., Knipe, K., Sammons, S.A., Ranganathan-Ganakammal, S., Srinivasamoorthy, G., Weil, M.R., Tatusov, R.L., Gee, J., Elrod, M.G., Hoffmaster, A.R., Weigel, L.M. 2015. Finished annotated genome sequence of *Burkholderia pseudomallei* strain Bp1651, a multidrug-resistant clinical isolate. *Genome Announc.* 3(6):e01427-15.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669406>

13. Conger NG, Paolino KM, Osborn EC, Rusnak JM, Gunther S, Pool J, Rollin PE, Allan PF, Schmidt-Chanasit J, Rieger T, and Kortepeter MG. Health Care Response to CCHF in US Soldier and Nosocomial Transmission to Health Care Providers, Germany, 2009. *Emerg Infect Dis.* 2015; 21(1):23-31
<http://www.ncbi.nlm.nih.gov/pubmed/25529825>

14. Connor MJ, Jr., Kraft C, Mehta AK, Varkey JB, Lyon GM, Crozier I, Stroher U, Ribner BS, Franch HA. 2015. Successful delivery of RRT in Ebola virus disease. *J Am Soc Nephrol* 2015; 26:31-37
<http://www.ncbi.nlm.nih.gov/pubmed/25398785>

15. Crowe S, Hertz D, Maenner M, Ratnayake R, Baker P, Lash RR, Klena J, Lee-Kwan SH, Williams C, Jonnie GT, Gorina Y, Anderson A, Saffa G, Carr D, Tuma J, Miller L, Turay A, Belay E. A Plan For Community Event-Based Surveillance to Reduce Ebola Transmission – Sierra Leone, 2014-2015. *Morb Mortal Wkly Rep.* 2015; 64(3):70-3. <http://www.ncbi.nlm.nih.gov/pubmed/25632956>

16. Dahlgren FS, Paddock CD, Springer YP, Eisen RJ, Behravesh CB. Expanding Range of *Amblyomma americanum* and Simultaneous Changes in the Epidemiology of Spotted Fever Group Rickettsiosis in the United States. *Am J Trop Med Hyg.* 2016 Jan 6; 94(1):35-42. doi: 10.4269/ajtmh.15-0580. Epub 2015 Oct 26. PubMed PMID: 26503270; PubMed Central PMCID: PMC4710442.
<http://www.ajtmh.org/content/94/1/35.long>

17. Deen GF, Knust B, Broutet N, Sesay FR, et al. Ebola RNA Persistence in Semen of Ebola Virus Disease Survivors - Preliminary Report. *N Engl J Med.* 2015 Oct 14. [Epub ahead of print]
<http://www.ncbi.nlm.nih.gov/pubmed/26465681>

18. Dentinger CM, Jacob K, Lee LV, Mendez HA, Chotikanatis K, McDonough PL, Chico DM, De BK, Tiller RV, Traxler RM, Campagnolo ER, Schmitt D, Guerra MA, Slavinski SA. Human *Brucella canis* Infection and Subsequent Laboratory Exposures Associated with a Puppy, New York City, 2012. *Zoonoses Public Health.* 2015 Aug;62(5):407-14. <http://onlinelibrary.wiley.com/doi/10.1111/zph.12163/epdf>

19. Devignot S, Bergeron E, Nichol S, Mirazimi A, Weber F. 2015. A virus-like particle system identifies the endonuclease domain of Crimean-Congo Hemorrhagic Fever virus. *J Virol* 2015; 89:5957-67.
<http://www.ncbi.nlm.nih.gov/pubmed/25810550>

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21. Duncan C, Gill VA, Worman K, Burek-Huntington K, Pabilonia KL, Johnson S, Fitzpatrick KA, Weller C, Kersh GJ. *Coxiella burnetii* exposure in northern sea otters *Enhydra lutris kenyoni*. *Dis Aquat Organ.* 2015 May 11;114(1):83-7. <http://www.ncbi.nlm.nih.gov/pubmed/25958809>

22. Dykes JK, Lúquez C, Raphael BH, McCroskey L, Maslanka SE. Laboratory Investigation of the First Case of Botulism Caused by *Clostridium butyricum* Type E Toxin in the United States. *J Clin Microbiol.* 2015 Oct;53(10):3363-5. doi: 10.1128/JCM.01351-15. Epub 2015 Aug 5. PMID:26246485
<http://jcm.asm.org/content/53/10/3363.full.pdf+html>

23. Eremeeva ME, Dasch GA. Challenges posed by tick-borne rickettsiae: eco-epidemiology and public health implications. *Front Public Health.* 2015 Apr 21;3:55. doi: 10.3389/fpubh.2015.00055. eCollection 2015. Review. PubMed PMID: 25954738; PubMed Central PMCID: PMC4404743
<http://dx.doi.org/10.3389/fpubh.2015.00055>

24. Falendysz EA, Lopera JG, Lorenzsonn F, Salzer JS, Hutson CL, Doty J, et al. Further Assessment of Monkeypox Virus Infection in Gambian Pouched Rats (*Cricetomys gam-bianus*) Using In Vivo Bioluminescent Imaging. (2015) *PLoS Negl Trop Dis* 9(10): e0004130. doi:10.1371/journal.pntd.0004130
<http://www.ncbi.nlm.nih.gov/pubmed/26517839>

25. Flint M, Goodman CH, Bearden S, Blau DM, et al. Ebola Virus Diagnostics: The US Centers for Disease Control and Prevention Laboratory in Sierra Leone, August 2014 to March 2015. *J Infect Dis.* 2015; 212 Suppl 2:S350-8. <http://www.ncbi.nlm.nih.gov/pubmed/26232439>

26. Florescu DF, Kalil AC, Hewlett AL, Schuh AJ, Stroher U, Uyeki TM, Smith PW. Administration of Brincidofovir and Convalescent Plasma in a Patient With Ebola Virus Disease. *Clin Infect Dis.* 2015; 61:969-973. <http://www.ncbi.nlm.nih.gov/pubmed/25991468>

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: Activities at this facility include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, vaccine evaluation, medical countermeasure evaluation, determining the natural history of infectious organisms and assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. More information can be found at: <http://www.cdc.gov/oid/>.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA, Overlap), Select Toxins (HHS), NIAID Category A pathogens

Outdoor Studies: Outdoor studies of biological aerosols were NOT conducted at the facility or off-site by facility personnel.

(viii) Briefly describe the publication policy of the facility:

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies>

CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: <http://aops-mas-iis.cdc.gov/Policy/Doc/policy516.pdf>

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Eisen RJ, Dennis DT, Gage KL. The role of early-phase transmission in the spread of *Yersinia pestis*. *J Med Entomol*. 2015 Nov; 52(6):1183-92. doi: 10.1093/jme/tjv128. Epub 2015 Aug 19. <http://www.ncbi.nlm.nih.gov/pubmed/26336267>
2. Fernandez-Gonzalez AM, Kosoy MY, Rubio AV, Graham CB, Montenieri JA, Osikowicz LM, Bai Y, Acosta-Gutierrez R, Avila-Flores R, Gage KL, Suzan G. Molecular survey of *Bartonella* species and *Yersinia pestis* in rodent fleas (Siphonaptera) from Chihuahua, Mexico. *J Med Entomol*. 2016; 53(1): 199-205. doi: 10.1093/jme/tjv181. <http://www.ncbi.nlm.nih.gov/pubmed/?term=Fernandez-Gonzalez+AM>
3. Jones, R.T., Borchert J, Eisen RJ, MacMillan K, Boegler KA, Gage KL. Flea-associated bacterial communities in a plague-endemic region of Uganda. *PLoS One*. 2015 Oct 20; 10(10):e0141057. doi: 10.1371/journal.pone.0141057. eCollection 2015. <http://www.ncbi.nlm.nih.gov/pubmed/26485147>
4. Kugeler KJ, Staples JE, Hinckley AF, Gage KL, Mead PS. Epidemiology of human plague in the United States, 1900-2012. 2015. Jan; 21(1):16-22. doi: 10.3201/eid2101.140564. <http://www.ncbi.nlm.nih.gov/pubmed/25529546>
5. Kwit N, Nelson C, Kugeler K, Petersen J, Plante L, Yaglom H, Kramer V, Schwartz B, House J, Colton L, Feldpausch A, Drenzek C, Baumbach J, DiMenna M, Fisher E, Debess E, Buttke D, Weinburke M, Percy C, Schriefer M, Gage K, Mead P. Human Plague – United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2015 Aug 28;64(33):918-9. <http://www.ncbi.nlm.nih.gov/pubmed/26313475>
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7. Moore SM, Monaghan A, Borchert JN, Mpanga JT, Atiku LA, Boegler KA, Montenieri J, MacMillan K, Gage KL, Eisen RJ. 2015. Seasonal fluctuations of small mammal and flea communities in a Ugandan plague focus: evidence to implicate *Arvicanthis niloticus* and *Crocidura* spp. as key hosts in *Yersinia pestis* transmission. *Parasit Vectors*. 2015; Jan 8; 8(1):11. doi: 10.1186/s13071-014-0616-1. <http://www.ncbi.nlm.nih.gov/pubmed/25573253>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: CDC's Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the Department of Health and Human Services (HHS) and HHS/U.S. Department of Agriculture overlap lists. Within CDC, DVBD has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance and detection of each agent and molecular and antigenic characterization. More information can be found at: <http://www.cdc.gov/ncecid/dvbd/>.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

Outdoor Studies: No outdoor studies of biological aerosols were conducted at the facility or off-site by facility personnel.

National biological defence research and development programmes

1. What is the name of the facility?

Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

2. Where is it located (include both address and geographical location)?

903 South 4th Street, Hamilton, Montana 59840

3. Floor area of laboratory areas by containment level:

BL2	1361 m ²
BL3	407 m ²
BL4	1145 m ²
Total laboratory floor area	2913 m ²

4. The organizational structure of each facility.

(i) Total number of personnel = 109

(ii) **Division of personnel:** **Military** = 0
Civilian = 109

(iii) Division of personnel by category:

Scientists = 47

Engineers = 0

Technicians = 57

Administrative and support staff = 5

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Entomology, Genetics, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Contractor staff = 5

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	\$19,842,451
Development	\$0
Test and evaluation	\$0

(viii) Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Barrenas F, Green RR, Thomas MJ, Law GL, Proll SC, Engelmann F, Messaoudi I, Marzi A, Feldmann H, Katze MG. Next-generation sequencing reveals a controlled immune response to Zaire Ebola virus challenge in cynomolgus macaques immunized with vesicular stomatitis virus expressing Zaire Ebola virus glycoprotein (VSVΔG/EBOVgp). *Clin Vaccine Immunol.* 2015 Mar;22(3):354-6. doi: 10.1128/CVI.00733-14. Epub 2015 Jan 14. PubMed PMID: 25589554; PubMed Central PMCID: PMC4340895.
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2. Baseler LJ, Falzarano D, Scott DP, Rosenke R, Thomas T, Munster VJ, Feldmann H, de Wit E. An Acute Immune Response to Middle East Respiratory Syndrome Coronavirus Replication Contributes to Viral Pathogenicity. *Am J Pathol.* 2015 Dec 24. pii: S0002-9440(15)00649-5. doi: 10.1016/j.ajpath.2015.10.025. [Epub ahead of print] PubMed PMID: 26724387. <http://www.ncbi.nlm.nih.gov/pubmed/26724387>
3. Best SM. Is the third interferon a charm? *Sci Transl Med.* 2015 Apr 22;7(284):284fs16. doi: 10.1126/scitranslmed.aaa2817. Epub 2015 Apr 22. PubMed PMID: 25904738.
<http://www.ncbi.nlm.nih.gov/pubmed/25904738>
4. Bibby K, Fischer RJ, Casson LW, Stachler E, Haas CN, Munster VJ. Persistence of Ebola Virus in Sterilized Wastewater. *Environ Sci Technol Lett.* 2015 Sep 8;2(9):245-249. Epub 2015 Aug 17. PubMed PMID: 26523283; PubMed Central PMCID: PMC4613737. <http://www.ncbi.nlm.nih.gov/pubmed/26523283>
5. Borisevich V, Lee B, Hickey A, DeBuysscher B, Broder CC, Feldmann H, Rockx B. Escape From Monoclonal Antibody Neutralization Affects Henipavirus Fitness In Vitro and In Vivo. *J Infect Dis.* 2016 Feb 1;213(3):448-55. doi: 10.1093/infdis/jiv449. Epub 2015 Sep 10. PubMed PMID: 26357909; PubMed Central PMCID: PMC4704671. <http://www.ncbi.nlm.nih.gov/pubmed/26357909>
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7. Chen L, Chavda KD, DeLeo FR, Bryant KA, Jacobs MR, Bonomo RA, Kreiswirth BN. Genome Sequence of a *Klebsiella pneumoniae* Sequence Type 258 Isolate with Prophage-Encoded *K. pneumoniae* Carbapenemase. *Genome Announc.* 2015 Jun 18;3(3). pii: e00659-15. doi: 10.1128/genomeA.00659-15. PubMed PMID: 26089425; PubMed Central PMCID: PMC4472902. <http://www.ncbi.nlm.nih.gov/pubmed/26089425>
8. Chesebro B, Striebel J, Rangel A, Phillips K, Hughson A, Caughey B, Race B. Early Generation of New PrPSc on Blood Vessels after Brain Microinjection of Scrapie in Mice. *MBio.* 2015 Sep 22;6(5):e01419-15. doi: 10.1128/mBio.01419-15. PubMed PMID: 26396245; PubMed Central PMCID: PMC4600122.
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11. Cross RW, Fenton KA, Geisbert JB, Ebihara H, Mire CE, Geisbert TW. Comparison of the Pathogenesis of the Angola and Ravn Strains of Marburg Virus in the Outbred Guinea Pig Model. *J Infect Dis.* 2015 Oct 1;212 Suppl 2:S258-70. doi: 10.1093/infdis/jiv182. Epub 2015 Jun 19. PubMed PMID: 26092858; PubMed Central PMCID: PMC4564542. <http://www.ncbi.nlm.nih.gov/pubmed/26092858>

12. Crowell J, Hughson A, Caughey B, Bessen RA. Host Determinants of Prion Strain Diversity Independent of Prion Protein Genotype. *J Virol*. 2015 Oct;89(20):10427-41. doi: 10.1128/JVI.01586-15. Epub 2015 Aug 5. PubMed PMID: 26246570; PubMed Central PMCID: PMC4580196.
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15. de Wit E, Munster VJ. Animal models of disease shed light on Nipah virus pathogenesis and transmission. *J Pathol*. 2015 Jan;235(2):196-205. doi: 10.1002/path.4444. Review. PubMed PMID: 25229234; PubMed Central PMCID: PMC4268059. <http://www.ncbi.nlm.nih.gov/pubmed/25229234>
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Rocky Mountain Laboratories hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program. More information is available at <http://www.niaid.nih.gov/about/organization/dir/rml/Pages/default.aspx>.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap, USDA), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes**1. What is the name of the facility?**

Integrated Research Facility at Fort Detrick (IRF-Frederick)

2. Where is it located (include both address and geographical location)?

8200 Research Plaza, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level:

BL-2	878 m ²
BL-3	0 m ²
BL-4	1305 m ²
Total laboratory floor area	2183 m ²

4. The organizational structure of each facility.

(i) **Total number of personnel** 91

(ii) **Division of personnel:**

Military	0
Civilian	91

(iii) **Division of personnel by category:**

Scientists	29
Engineers	2
Technicians	53
Administrative and support staff	7

(iv) **List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology, Aerosol Science, Analytical Biochemistry, Biochemistry, Biological Science, Cell Biology, Immunology, Medicine, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine

(v) **Are contractor staff working in the facility? If so, provide an approximate number.**

Contractor staff = 80

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Health and Human Services (HHS)

(vii) **What are the funding levels for the following programme areas:**

Research	\$19,261,144
Development	\$0
Test and evaluation	\$0

(viii) **Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science

and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. Bohannon JK, Lackemeyer MG, Kuhn JH, Wada J, Bollinger L, Jahrling PB, Johnson RF. Generation and characterization of large-particle aerosols using a center flow tangential aerosol generator with a non-human-primate, head-only aerosol chamber. *Inhal Toxicol.* 2015; 27(5):247-53. doi: 10.3109/08958378.2015.1033570. Epub 2015 May 13. <http://www.ncbi.nlm.nih.gov/pubmed/25970823>
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3. Falcinelli S, Gowen BB, Trost B, Napper S, Kusalik A, Johnson RF, Saffronetz D, Prescott J, Wahl-Jensen V, Jahrling PB, Kindrachuk J. Characterization of the host response to pichinde virus infection in the Syrian golden hamster by species-specific kinome analysis. *Mol Cell Proteomics.* 2015 Mar; 14(3):646-57. doi: 10.1074/mcp.M114.045443. Epub 2015 Jan 8. <http://www.ncbi.nlm.nih.gov/pubmed/25573744>
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7. Johnson RF, Via LE, Kumar MR, Cornish JP, Yellayi S, Huzella L, Postnikova E, Oberlander N, Bartos C, Ork BL, Mazur S, Allan C, Holbrook MR, Solomon J, Johnson JC, Pickel J, Hensley LE, Jahrling PB. Intratracheal exposure of common marmosets to MERS-CoV Jordan-n3/2012 or MERS-CoV EMC/2012 isolates does not result in lethal disease. *Virology.* 2015 Nov; 485:422-30. doi: 10.1016/j.virol.2015.07.013. Epub 2015 Sep 3. <http://www.ncbi.nlm.nih.gov/pubmed/26342468>
8. Kuhn JH, Lauck M, Bailey AL, Shchetinin AM, Vishnevskaya TV, Bào Y, Ng TF, LeBreton M, Schneider BS, Gillis A, Tamoufe U, Diffo JL, Takuo JM, Kondov NO, Coffey LL, Wolfe ND, Delwart E, Clawson AN, Postnikova E, Bollinger L, Lackemeyer MG, Radoshitzky SR, Palacios G, Wada J, Shevtsova ZV, Jahrling PB, Lapin BA, Deriabin PG, Dunowska M, Alkhovsky SV, Rogers J, Friedrich TC, O'Connor DH, Goldberg TL. Reorganization and expansion of the nidoviral family Arteriviridae. *Arch Virol.* 2015 Nov 25. <http://www.ncbi.nlm.nih.gov/pubmed/26608064>
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Fort Detrick in Frederick, Maryland manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Batelle Memorial Institute facilitates research performed at the IRF-Frederick with direction from the IRF Scientific Steering Committee.

Microorganisms and/or Toxins Studied: Select Agents (HHS, USDA, Overlap), NIAID Category A pathogens
Outdoor studies: No outdoor studies of biological aerosols were conducted.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

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123. Xiong X, Corti D, Liu J, Pinna D, Foglierini M, Calder LJ, Martin SR, Lin YP, Walker PA, Collins PJ, Monne I, Sugitan AL Jr, Santos C, Temperton NJ, Subbarao K, Lanzavecchia A, Gamblin SJ, Skehel JJ. Structures of complexes formed by H5 influenza hemagglutinin with a potent broadly neutralizing human monoclonal antibody. *Proc Natl Acad Sci U S A.* 2015 Jul 28;112(30):9430-5. doi: 10.1073/pnas.1510816112. Epub 2015 Jul 13. PubMed PMID: 26170284; PubMed Central PMCID: PMC4522749. <http://www.ncbi.nlm.nih.gov/pubmed/26170284>

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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: At the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, the Laboratory of Infectious Diseases (LID) focuses on vaccine development, host immune response to viruses, and viral molecular biology and genetics. The Laboratory of Parasitic Diseases (LPD) conducts basic and applied research on the prevention, control, and treatment of a variety of parasitic and bacterial diseases of global importance. The Laboratory of Viral Diseases (LVD) carries out investigations on the molecular biology of viruses, the interactions of viruses with host cells, the pathogens of viral diseases, and host defense mechanisms. The Laboratory of Clinical Infectious Diseases (LCID) conducts clinical and basic studies of important human infections and immunological diseases. The Laboratory of Bacteriology (LB) studies bacteria that cause important human infections to identify novel or improved strategies to control bacterial diseases, including development of diagnostics, vaccines, and therapeutics. More information can be found at <http://www.nih.gov/news-events/news-releases/nih-dedicates-cw-bill-young-center-biodefense-emerging-infectious-diseases>.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA), NIAID Category A pathogen

Outdoor studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes

1. What is the name of the facility?

Dale and Betty Bumpers Vaccine Research Center (VRC)

2. Where is it located (include both address and geographical location)?

National Institutes of Health, Department of Health and Human Services
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:

4. The organizational structure of each facility.

(i) **Total number of personnel** = 8

(ii) **Division of personnel:** **Military** = 0
Civilian = 8

(iii) Division of personnel by category:

Scientists = 8

Engineers = 0

Technicians = 0

Administrative and support staff = 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.

Biological Science

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Contractor staff = 1

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	\$1,081,718
Development	0
Test and evaluation	0

(viii) Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.)

1. De Santis O, Audran R, Pothin E, Warpelin-Decrausaz L, Vallotton L, Wuerzner G, Cochet C, Estoppey D, Steiner-Monard V, Lonchampt S, Thierry AC, Mayor C, Bailer RT, Mbaya OT, Zhou Y, Ploquin A, Sullivan NJ, Graham BS, Roman F, De Ryck I, Ballou WR, Kieny MP, Moorthy V, Spertini F, Genton B. Safety and immunogenicity of a chimpanzee adenovirus-vectored Ebola vaccine in healthy adults: a randomised, double-blind, placebo-controlled, dose-finding, phase 1/2a study. *Lancet Infect Dis.* 2015 Dec 22. pii: S1473-3099(15)00486-7. doi: 10.1016/S1473-3099(15)00486-7. [Epub ahead of print] PubMed PMID: 26725450. <http://www.ncbi.nlm.nih.gov/pubmed/26725450>
2. Ledgerwood JE, Sullivan NJ, Graham BS. Chimpanzee Adenovirus Vector Ebola Vaccine--Preliminary Report. *N Engl J Med.* 2015 Aug 20; 373(8):776. doi: 10.1056/NEJMc1505499. PubMed PMID: 26287857. <http://www.ncbi.nlm.nih.gov/pubmed/26287857>
3. Liang F, Ploquin A, Hernández JD, Fausther-Bovendo H, Lindgren G, Stanley D, Martinez AS, Brenchley JM, Koup RA, Loré K, Sullivan NJ. Dissociation of skeletal muscle for flow cytometric characterization of immune cells in macaques. *J Immunol Methods.* 2015 Oct; 425:69-78. doi: 10.1016/j.jim.2015.06.011. Epub 2015 Jun 20. PubMed PMID: 26099800; PubMed Central PMCID: PMC4604051. <http://www.ncbi.nlm.nih.gov/pubmed/26099800>
4. Rampling T, Ewer K, Bowyer G, Wright D, Imoukhuede EB, Payne R, Hartnell F, Gibani M, Bliss C, Minhinnick A, Wilkie M, Venkatraman N, Poulton I, Lella N, Roberts R, Sierra-Davidson K, Krähling V, Berrie E, Roman F, De Ryck I, Nicosia A, Sullivan NJ, Stanley DA, Ledgerwood JE, Schwartz RM, Siani L, Colloca S, Folgori A, Di Marco S, Cortese R, Becker S, Graham BS, Koup RA, Levine MM, Moorthy V, Pollard AJ, Draper SJ, Ballou WR, Lawrie A, Gilbert SC, Hill AV. A Monovalent Chimpanzee Adenovirus Ebola Vaccine - Preliminary Report. *N Engl J Med.* 2015 Jan 28. [Epub ahead of print] PubMed PMID: 25629663. <http://www.ncbi.nlm.nih.gov/pubmed/25629663>
5. Regules JA, Beigel JH, Paolino KM, Voell J, Castellano AR, Muñoz P, Moon JE, Ruck RC, Bennett JW, Twomey PS, Gutiérrez RL, Remich SA, Hack HR, Wisniewski ML, Joslyn MD, Kwiłas SA, Van Deusen N, Mbaya OT, Zhou Y, Stanley DA, Bliss RL, Cebrik D, Smith KS, Shi M, Ledgerwood JE, Graham BS, Sullivan NJ, Jagodzinski LL, Peel SA, Alimonti JB, Hooper JW, Silvera PM, Martin BK, Monath TP, Ramsey WJ, Link CJ, Lane HC, Michael NL, Davey RT Jr, Thomas SJ; rVSVΔG-ZEBOV-GP Study Group. A Recombinant Vesicular Stomatitis Virus Ebola Vaccine – Preliminary Report. *N Engl J Med.* 2015 Apr 1. [Epub ahead of print] PubMed PMID: 25830322. <http://www.ncbi.nlm.nih.gov/pubmed/25830322>
6. Tapia MD, Sow SO, Lyke KE, Haidara FC, Diallo F, Doumbia M, Traore A, Coulibaly F, Kadio M, Onwuchekwa U, Sztein MB, Wahid R, Campbell JD, Kieny MP, Moorthy V, Imoukhuede EB, Rampling T, Roman F, De Ryck I, Bellamy AR, Dally L, Mbaya OT, Ploquin A, Zhou Y, Stanley DA, Bailer R, Koup RA, Roederer M, Ledgerwood J, Hill AV, Ballou WR, Sullivan N, Graham B, Levine MM. Use of ChAd3-EBO-Z Ebola virus vaccine in Malian and US adults, and boosting of Malian adults with MVA-BN-Filo: a phase 1, single-blind, randomised trial, a phase 1b, open-label and double-blind, dose-escalation trial, and a nested, randomised, double-blind, placebo-controlled trial. *Lancet Infect Dis.* 2016 Jan; 16(1):31-42. doi: 10.1016/S1473-3099(15)00362-X. Epub 2015 Nov 4. PubMed PMID: 26546548; PubMed Central PMCID: PMC4700389. <http://www.ncbi.nlm.nih.gov/pubmed/26546548>
7. Zhou Y, Sullivan NJ. Immunology and evolution of the adenovirus prime, MVA boost Ebola virus vaccine. *Curr Opin Immunol.* 2015 Aug; 35:131-6. doi: 10.1016/j.co.2015.06.006. Epub 2015 Aug 3. Review. PubMed PMID: 26247875. <http://www.ncbi.nlm.nih.gov/pubmed/26247875>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The mission of the Vaccine Research Center (VRC) is to conduct research that facilitates the development of effective vaccines for human disease. The research focus of the Biodefense Research Section comprises three areas: development of vaccines and antivirals against hemorrhagic fever viruses such as Ebola, Marburg, and Lassa; studies of the mechanism of vaccine-induced immune protection and host immunity to natural infection; basic research to understand the mechanism of virus replication (entry) and neutralization. More information can be found at

<http://www.niaid.nih.gov/about/organization/vrc/pages/default.aspx/Pages/default.aspx>.

Microorganisms and/or toxins studied: No U.S. Select Agents, NIAID Category A pathogens, or applicable simulants were used.

Outdoor studies: No outdoor studies of biological aerosols were conducted.

National biological defence research and development programmes: Facilities**1. What is the name of the facility?**

Foreign Disease-Weed Science Research Unit

2. Where is it located (provide both address and geographical location)?

1301 Ditto Avenue, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	105 m ²
BSL-3:	950 m ²
BSL-4:	0 m ²
Total laboratory floor area:	1,055 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 28

(ii) **Division of personnel:**

Military	0
Civilian	28

(iii) **Division of personnel by category:**

Scientists	10
Engineers	
Technicians	13
Administrative and support staff	5

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Agronomy, Biological Science, Genomics, Horticulture, Bacteriology, Microbial Forensics, Molecular Diagnostics, Plant Biochemistry, Plant Molecular Biology, Plant Pathology, Plant Physiology, Proteomics, Virology, Weed Science

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

No.

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture (USDA)

(vii) **What are the funding levels for the following program areas:**

Research	\$4,000,000
Development	\$0
Test and evaluation	\$0
Total	\$4,000,000

(viii) **Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA

Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at <http://www.ars.usda.gov/services/services.htm?modecode=80-44-05-00&locpubs=yes>).

(ix) Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):

1. Berner DK, Smallwood EL, Vanrenterghem M, Cavin CA, Michael JL, Shelley BA, Kolomiets T, Pakratova L, Bruckart WL, Mukhina Z. 2015. Some dynamics of spread and infection by aeciospores of *Puccinia punctiformis*, a biological control pathogen of *Cirsium arvense*. *Biological Control*. 88:18-25. <http://www.sciencedirect.com/science/article/pii/S1049964415000936>
2. Bruckart WL, Michael JL, Coombs EM, Pirosko CB. 2015. Rust pathogen *Puccinia jaceae* is established on Yellow Starthistle (*Centaurea solstitialis*) in Oregon. *Plant Disease*. doi.org/10.1094/PDIS-09-15-1042-PDN. <http://apsjournals.apsnet.org/doi/full/10.1094/PDIS-09-15-1042-PDN?prevSearch=%24{resultBean.text}&searchHistoryKey=%24{searchHistoryKey}>
3. Harris DK, Kendrick MD, King ZR, Pedley KF, Walker DR, Cregan PB, Buck JW, Phillips DV, Li Z, Boerma H. 2015. Identification of unique genetic sources of soybean rust resistance from the USDA germplasm collection. *Crop Science*. DOI: 10.2135/cropsci2014.09.0671. <https://dl.sciencesocieties.org/publications/cs/abstracts/55/5/2161>
4. King ZR, Harris DK, Pedley KF, Song Q, Wang D, Wen Z, Buck JW, Li Z, Boerma H. 2015. A Novel Phakopsora pachyrhizi Resistance Allele (Rpp) Contributed by PI 567068A. *Theoretical and Applied Genetics*. DOI 10.1007/s00122-015-2645-3. <http://link.springer.com/article/10.1007/s00122-015-2645-3>
5. Paul C, Frederick RD, Hill CB, Hartman GL, Walker DR. 2015. Comparison of pathogenic variation among Phakopsora pachyrhizi isolates collected from the United States and International Locations, and identification of Soybean genotypes resistant to the United States isolates. *Plant Disease*. 99(8): 1059-1069. <http://apsjournals.apsnet.org/doi/abs/10.1094/PDIS-09-14-0989-RE>
6. Roy A, Hartung JS, Schneider WL, Shao JY, Leon GM, Melzer MJ, Beard JJ, Otero-Colina G, Bauchan GR, Ochoa R, Bransky RH. 2015. Role bending: complex relationships between viruses, hosts and vectors related to citrus leprosis, an emerging disease. *Phytopathology*. DOI: 10.1094/PHYTO-12-14-0375-FI. <http://apsjournals.apsnet.org/doi/abs/10.1094/PHYTO-12-14-0375-FI>
7. Roy A, Stone AL, Shao JY, Colina G, Wei G, Choudary N, Achor D, Nakhla M, Levy L, Hartung JS, Schneider WL, Bransky R. 2015. Identification and molecular characterization of nuclear Citrus leprosis virus, an unassigned Dichorhavirus genus member associated with citrus leprosis disease in Mexico. *Virus Research*. 105:564-575. <http://apsjournals.apsnet.org/doi/abs/10.1094/PHYTO-09-14-0245-R>
8. Tooley PW, Browning ME. 2015. Temperature effects on the onset of sporulation by *Phytophthora ramorum* on rhododendron Cunningham's White. *Journal of Phytopathology*. DOI: 10.1111/jph.12390. <http://onlinelibrary.wiley.com/doi/10.1111/jph.12390/abstract;jsessionid=D3EB6485973BA35273A364AB1D2E707B.f02t03?userIsAuthenticated=false&deniedAccessCustomisedMessage=>
9. Widmer TL. 2015. Differences in virulence and sporulation of *Phytophthora kernoviae* isolates originating from two distinct geographical regions. *Plant Disease*. 99:460-466. <http://apsjournals.apsnet.org/doi/abs/10.1094/PDIS-09-14-0957-RE>
10. Widmer TL, Dodge SC. 2015. Bioassay conditions for infection of *Pinus radiata* seedlings with *Phytophthora pinifolia* zoospores. *Plant Disease*. 99:1204-1209. <http://apsjournals.apsnet.org/doi/abs/10.1094/PDIS-12-14-1306-RE>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: The Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's unique BL-3 plant pathogen laboratory and greenhouse containment facilities. 1) The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm. 2) The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides. Additional information about research projects conducted at this location is available at

http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00.

Microorganisms and/or Toxins Studied: Select Agents (Plant Protection and Quarantine, PPQ)

Outdoor Studies: No research work is done outdoors with infectious organisms.

National biological defence research and development programmes: Facilities**1. What is the name of the facility?**

National Animal Disease Center (NADC)

2. Where is it located (provide both address and geographical location)?

1920 Dayton Avenue, Ames, Iowa 50010

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	4,410 m ²
BSL-3:	2,489 m ²
BSL-4:	0 m ²
Total laboratory floor area:	6,899 m ²

In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level that can accommodate food producing animals and various wildlife species).

Biocontainment enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in/out of each animal room; heat-treated waste; steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors; and epoxy-covered surfaces. NADC also has two large biocontainment buildings that are considered ABSL-2-enhanced.

ABSL-2:	3,467.7 m ²
ABSL-3:	160.5 m ²
ABSL-3Ag:	1,581.6 m ²
Total biocontainment facility floor area:	5209.8 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 48

(ii) **Division of personnel:**

Military	0
Civilian	48

(iii) **Division of personnel by category:**

Scientists	8
Engineers	1
Technicians	10
Administrative and support staff	29

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Agricultural Engineering, Animal Science, Biochemistry, Bioinformatics, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Ecology, Genetics, Genomics, Immunology, Infectious Disease, Mass Spectrometry, Microbiology, Molecular Biology, Pathogenesis, Pathology, Physiology, Prionology, Proteomics, Statistics, Structural Biology, Vaccine Evaluation, Veterinarian, Veterinary Clinical Research, Veterinary Medicine, Virology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**

No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture (USDA)
Department of Defense (DoD) – partly
Department of Health and Human Services (HHS)
Universities
Private Sector Companies

(vii) **What are the funding levels for the following program areas:**

Research	\$5,800,000
Development	\$0
Test and evaluation	\$0
Total	\$5,800,000

(viii) **Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at

<http://www.ars.usda.gov/services/services.htm?modecode=50-30-20-00&locpubs=yes>).

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Allen HK, An R, Handelsman J, Moe L. 2015. A response regulator from a soil metagenome enhances resistance to the beta-lactam antibiotic carbenicillin in *Escherichia coli*. *PLoS One*. 10(3):e0120094. DOI: 10.1371/journal.pone.0120094. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0120094>
2. Alt DP, Wilson-Welder JH, Bayles DO, Cameron C, Adler B, Bulach DM, Seemann T, Lehane MJ, Haines LR, Darby AC, Hall N, Radford AD, Zuerner RL. 2015. Complete genome sequence of *Leptospira interrogans* serovar Bratislava, strain PigK151. *Genome Announcements*. 3(3):e00678-15. DOI: 10.1128/genomeA.00678-15. <http://genomea.asm.org/content/3/3/e00678-15.short>
3. Bannantine JP, Stabel JR, Laws E, Cardieri MC, Souza C. 2015. *Mycobacterium avium* subspecies *paratuberculosis* recombinant proteins modulate antimycobacterial functions of bovine macrophages. *PLoS One*. DOI: 10.1371/journal.pone.0128966. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0128966>
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5. Bao H, Kommadath A, Liang G, Sun X, Arantes AS, Tuggle CK, Plastow GS, Bearson SM, Stothard P, Guan L. 2015. Genome-wide whole blood microRNAome and transcriptome analyses reveal miRNA-mRNA regulated host response to foodborne pathogen *Salmonella* infection in swine. *Scientific Reports*. 5:12620. doi: 10.1038/srep12620. <http://www.nature.com/articles/srep12620>
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<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0129740>
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<http://cvi.asm.org/content/22/6/641.short>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Support the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis. Specifically, the research programs aim to produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases. Additional information about research projects conducted at this location is available at

http://www.ars.usda.gov/research/projects_programs.htm?modecode=50-30-20-00.

Microorganisms and/or Toxins Studied: Select Agents (Overlap, USDA)

Outdoor Studies: No research work is done outdoors with infectious organisms.

National biological defence research and development programmes: Facilities**1. What is the name of the facility?**

Southeast Poultry Research Laboratory

2. Where is it located (provide both address and geographical location)?

934 College Station Road, Athens, Georgia 30605

3. Floor area of laboratory areas by containment level (m²):

BSL-2:	1,138 m ²
BSL-3:	624 m ²
BSL-4:	0 m ²
Total laboratory floor area:	1,762 m ²

4. The organizational structure of each facility:

(i) **Total number of personnel:** 37

(ii) **Division of personnel:**
Military
Civilian 37

(iii) **Division of personnel by category:**
Scientists 10
Engineers 0
Technicians 18
Administrative and support staff 9

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**

Animal Science, Bioinformatics, Biological Science, Biotechnology, Cell Biology, Computational Biology, Epidemiology, Genetics, Genomics, Immunology, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology

(v) **Are contractor staff working in the facility? If so, provide an approximate number:**
No

(vi) **What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**
U.S. Department of Agriculture (USDA)
Department of Health and Human Services (HHS)
Department of Defense (DoD) – partly
Non-Profit Associations
Private Sector Companies
Department of State

(vii) **What are the funding levels for the following program areas:**

Research	\$3,700,000
Development	\$0
Test and evaluation	\$0
Total	\$3,700,000

(viii) **Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at <http://www.ars.usda.gov/services/services.htm?modecode=60-40-10-00&locpubs=yes>).

(ix) **Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.):**

1. Bertran K, Moresco KA, Swayne DE. 2015. Impact of vaccination on infection with Vietnam H5N1 high pathogenicity avian influenza virus in hens and the eggs they lay. *Vaccine*. 33(11):1324-1330.
<http://www.ncbi.nlm.nih.gov/pubmed/25657093>
2. Bertran K, Thomas C, Guo X, Bublot M, Pritchard N, Regan JT, Cox KM, Gasdaska JR, Dickey LF, Kapczynski DR, Swayne DE. 2015. Expression of H5 hemagglutinin vaccine antigen in common duckweed (*Lemna minor*) protects against H5N1 high pathogenicity avian influenza virus challenge in immunized chickens. *Vaccine*. 33(30):3456-3462. doi:10.1016/j.vaccine.2015.05.076.
<http://www.ncbi.nlm.nih.gov/pubmed/26067184>
3. Costa-Hurtado M, Afonso CL, Miller PJ, Shepherd EM, Cha R, Smith DM, Spackman E, Kapczynski DR, Suarez DL, Swayne DE, Pantin Jackwood MJ. 2015. Previous infection with virulent strains of Newcastle disease virus reduces highly pathogenic avian influenza virus replication, disease, and mortality in chickens. *Veterinary Research*. 46:97. doi: 10.1186/s13567-015-0237-5.
<http://www.ncbi.nlm.nih.gov/pubmed/26394750>
4. Hutchesson JM, Susta L, Stice SL, Afonso CL, West FD. 2015. Delayed Newcastle disease virus replication using RNA interference to target the nucleoprotein. *Biologicals*. 43(4):274-280. doi: 10.1016/j.biologicals.2015.03.004. <http://www.ncbi.nlm.nih.gov/pubmed/26050911>
5. Kapczynski DR, Esaki M, Dorsey K, Jiang H, Jackwood M, Moraes M, Gardin Y. 2015. Vaccine protection of chickens against antigenically diverse H5 highly pathogenic avian influenza isolates with a live HVT vector vaccine expressing the influenza hemagglutinin gene derived from a clade 2.2 avian influenza vi. *Vaccine*. 33(9):1197-1205. doi: 10.1016/j.vaccine.2014.12.028.
<http://www.ncbi.nlm.nih.gov/pubmed/25613723>
6. Lee D, Torchetti M, Winker K, Ip HS, Song C, Swayne DE. 2015. Intercontinental spread of Asian-origin H5N8 to North America through Beringia by migratory birds. *Journal of Virology*. 89(12):6521-6524. doi: 10.1128/JVI.00728-15. <http://www.ncbi.nlm.nih.gov/pubmed/25855748>
7. Machalaba CM, Elwood S, Forcella S, Smith K, Hamilton K, Jabara K, Swayne DE, Webby RJ, Mumford E, Mazet J, Gaidet N, Daszak P, Karesh WB. 2015. Global avian influenza surveillance in wild birds: A strategy to capture viral diversity. *Emerging Infectious Diseases*. 21(4):e1-7.
<http://www.ncbi.nlm.nih.gov/pubmed/25811221>
8. Moura V, Susta L, Cardenas-Garcia S, Stanton J, Miller PJ, Afonso CL, Brown C. 2015. Neuropathogenic capacity of lentogenic, mesogenic, and velogenic Newcastle disease virus strains in day-old chickens. *Veterinary Pathology*. doi: 10.1177/0300985815600504.
<http://www.ncbi.nlm.nih.gov/pubmed/26395462>
9. Pantin Jackwood MJ, Costa-Hurtado M, Miller PJ, Afonso CL, Spackman E, Kapczynski DR, Shepherd EM, Smith DM, Swayne DE. 2015. Experimental co-infections of domestic ducks with a virulent Newcastle disease virus and low or highly pathogenic avian influenza viruses. *Veterinary Microbiology*. 177:7-17. <http://www.ncbi.nlm.nih.gov/pubmed/25759292>
10. Rehmani SF, Wajid A, Bibi T, Nazir B, Mukhtar N, Hussain A, Lone N, Yaqub T, Afonso CL. 2015. Presence of virulent Newcastle disease virus in vaccinated chickens in farms in Pakistan. *Journal of Clinical Microbiology*. 53(5):1715-1718. doi: 10.1128/JCM.02818-14.
<http://www.ncbi.nlm.nih.gov/pubmed/25694525>

11. Spackman E, Pantin Jackwood MJ, Swayne DE, Suarez DL, Kapczynski DR. 2015. Impact of route of exposure and challenge dose on the pathogenesis of H7N9 low pathogenicity avian influenza virus in chickens. *Virology*. 477:72-81.
<http://www.sciencedirect.com/science/article/pii/S0042682215000148>
12. Susta L, Diel D, Courtney S, Cardenas-Garcia S, Sundick R, Miller PJ, Brown C, Afonso CL. 2015. Expression of chicken interleukin-2 by a highly virulent strain of Newcastle disease virus leads to decreased systemic viral load but does not significantly affect mortality in chickens. *Virology Journal*. 12:122. DOI: 10.1186/s12985-015-0353-x. <http://www.ncbi.nlm.nih.gov/pubmed/26253150>
13. Swayne DE, Suarez DL, Spackman E, Jadhao S, Dauphin G, Kim-Torchetti M, McGrane J, Weaver J, Daniels P, Wong F, Selleck P, Wiyono A, Indriani R, Yupiana Y, Sawitri Siregar E, Prajitno T, Smith D, Fouchier R. 2015. Antibody titer has positive predictive value for vaccine protection against challenge with natural antigenic-drift variants of H5N1 high-pathogenicity avian influenza viruses from Indonesia. *Journal of Virology*. 89(7):3746-3762. doi: 10.1128/JVI.00025-15.
<http://www.ncbi.nlm.nih.gov/pubmed/25609805>
14. Wajid A, Wasim M, Rehmani S, Bibi T, Ahmed N, Afonso CL. 2015. Complete genome sequence of a recent panzootic virulent Newcastle disease virus from Pakistan. *Genome Announcements*. 3(3):e00658-15. doi: 10.1128/genomeA.00658-15. <http://www.ncbi.nlm.nih.gov/pubmed/26089424>
15. Weaver J, Malladi S, Spackman E, Swayne DE. 2015. Risk reduction modeling of high pathogenicity avian influenza virus titers in non-pasteurized liquid egg obtained from infected but undetected chicken flocks. *Risk Analysis*. doi: 10.1111/risa.12374. <http://www.ncbi.nlm.nih.gov/pubmed/25867713>

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies; prediction of disease outbreaks; molecular epidemiology; and understanding of disease pathogenesis. Produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations; develop more sensitive, specific and faster diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and improve our understanding of the genetic and pathobiological basis of virulence. This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has one research unit that conducts biological defense work: Exotic and Emerging Avian Viral Diseases Research Unit. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/main/site_main.htm?modecode=60-40-10-00.

Microorganisms and/or Toxins Studied: Select Agents (USDA)

Outdoor Studies: No research work is done outdoors with infectious organisms.

Form B

BWC - Confidence Building Measure

Exchange of information on outbreaks of infectious diseases and similar occurrences caused by toxins

United States of America

April 15, 2016

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Human Infection with Novel Influenza A(H1N1)v:**

On May 12, 2015, the U.S. National Focal Point was notified of a case of human infection with a novel influenza A(H1N1) variant virus.

On April 15, 2015, a 27 year-old male with medical history significant for tobacco use and obesity developed an acute respiratory illness in Ohio. He first sought healthcare on April 18, and was eventually hospitalized on April 20, 2015. While hospitalized, his clinical course was notable for pneumonia, respiratory failure, and cardiac arrest. He did not have evidence of bacterial infection secondary to his primary viral pneumonia. His condition continued to worsen over the course of his hospitalization and he died on April 27, 2015.

A lower respiratory tract specimen obtained on April 21, 2015, yielded initial results positive for influenza A(H1N1)pdm09 virus (a seasonal influenza virus) on multiplex testing done on April 21, 2015, but subsequent RT-PCR testing at the state public health laboratory on April 30, 2015 was suggestive of a novel influenza A virus. Additional RT-PCR testing conducted at CDC on May 2, 2015, confirmed infection with an H1N1v virus of classical swine origin. Subsequent partial genetic sequencing conducted at CDC on May 3, 2015, indicated infection with an A(H1N1)v virus similar to influenza A(H1N1) viruses currently circulating in swine.

This was the first variant influenza virus infection reported in the United States in 2015. Since reporting of novel influenza viruses became nationally notifiable in 2005, 20 cases of H1N1v, including this one, have been reported to CDC. This is the first H1N1v-associated fatality.

The patient worked at a livestock facility that housed cattle and swine but did not have direct contact with swine in the week prior to his illness onset, according to his employer. No illness was reported in the patient's household or close contacts, his co-workers, or the healthcare workers who cared for him during his illness. An investigation into the source of the patient's infection and to determine if there were other epidemiologically-linked cases of H1N1v virus infection was conducted. Further genetic sequencing of the virus was also conducted at CDC.

Swine-origin influenza A viruses currently circulate among North American swine herds. Human infections with these viruses (i.e., variant virus infections) are rarely detected, and cases usually occur following direct or close contact with pigs. Since 2005, a total of 379 variant virus infections have been identified in the United States; the current case was only the second variant influenza fatality reported. There has been limited, non-sustained human-to-human transmission of variant influenza viruses, but no ongoing community transmission has been identified.

General information about variant and swine influenza is available <http://www.cdc.gov/flu/swineflu/index.htm>.

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Human Infection with Novel Influenza A (H3N2v):**

On July 29, 2015, the U.S. National Focal Point was notified of a case of human infection with influenza A (H3N2) variant (H3N2v) virus.

On July 3, 2015, a 10 year-old male with medical history significant for cancer (and immune compromise subsequent to chemotherapy) developed an acute respiratory illness in Minnesota. He was hospitalized for his illness on July 3, and on July 6, treatment with oseltamivir was initiated. An upper respiratory tract specimen obtained on July 6, 2015, yielded results consistent with an H3N2v virus on RT-PCR testing conducted at the state public health laboratory on July 16, 2015. Additional RT-PCR testing conducted at CDC on July 20, 2015, confirmed infection with an H3N2v virus. This was the first H3N2v virus infection reported in the United States in 2015.

The patient's family resides on a farm with swine, and the patient reported direct contact with swine in the week prior to his illness onset. No illness was reported in the patient's household or close contacts or in healthcare workers caring for him during his illness. An investigation into the source of the patient's infection and to determine if there are other epidemiologically-linked cases of H3N2v virus infection was conducted. Additional laboratory testing, including genetic sequencing of the virus, was conducted at CDC.

Swine influenza is a respiratory disease of pigs caused by influenza A viruses that regularly cause outbreaks of influenza in pigs. Human infections with these viruses (i.e., variant virus infections) are rarely detected and usually only occur in people with exposure to infected pigs. There has been limited, non-sustained, human-to-human transmission of variant influenza viruses, and no ongoing community transmission has been identified. General information about variant and swine influenza is available <http://www.cdc.gov/flu/swineflu/index.htm>.

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Inadvertent Shipment of Live *Bacillus anthracis* to Laboratories in Multiple U.S. and Overseas Locations:**

On May 31, 2015, the U.S. IHR National Focal Point officially reported an inadvertent shipment of live *Bacillus anthracis* (anthrax) to laboratories in multiple U.S. and overseas locations. Although this event did not meet at least two criteria for an IHR Article 6 notification and did not constitute a public health emergency of international concern, the United States shared this information under Article 7, regarding an unexpected event for the information of member Nations.

The U.S. Department of Defense (DoD) collaborated with the U.S. Centers for Disease Control and Prevention (CDC) to investigate an inadvertent shipment of live anthrax samples from a DoD laboratory to laboratories in multiple U.S. states and overseas locations. The DoD Chemical and Biological Defense Program (CBDP) develops medical and physical countermeasures to protect the warfighter and the nation from chemical and biological threats. As part of this mission, DoD regularly ships inactivated or “killed” biological materials for countermeasure development by industry, academia, and other federal laboratories.

On May 22, 2015, CDC was notified by a biotechnology company in Maryland, reporting that it had been able to culture small amounts of live anthrax bacteria from samples sent to them as part of a DoD test, although all samples were supposed to have been inactivated. CDC, as the nation’s public health lead and regulatory authority for biological select agents and toxins, began working with DoD, private laboratories, state officials, and the Federal Bureau of Investigation (FBI) to investigate all laboratories known to have received this suspect sample. Ultimately, laboratory samples of anthrax that were thought to have been killed, but were later found to contain a small amount of live anthrax, were sent by a DoD laboratory to 194 laboratories and 9 countries.

As part of CDC’s response, CDC

- Ensured that people were safe, by working with state health departments to identify potentially exposed workers, assess their health risk, and offer treatment when appropriate;
- Developed recommendations for effective decontamination of laboratories, in collaboration with the Environmental Protection Agency (EPA); and
- Secured the samples of live anthrax inadvertently sent to places not approved to have live anthrax or any select agent, to prevent any further potential exposures.

CDC does not suspect any risk to the general public. There are no suspected or confirmed cases of anthrax infection in potentially exposed laboratory workers.

The Federal Select Agent Program (FSAP), jointly comprised of CDC’s Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS), issued a moratorium on the use and transfer of inactivated *B. anthracis* to prevent inadvertent exposure until safer and more effective procedures regarding inactivated *B. anthracis* can be developed based on the interagency scientific discussion and research into the matter.

FSAP also developed a policy regarding the “Inactivation of *Bacillus anthracis*” (http://www.selectagents.gov/policystatement_bacillus.html). The policy states that all vegetative cell and spore preparations of *Bacillus anthracis* strains will be regulated as select agents. HHS and USDA plan to publish Notices of Proposed Rulemaking (NPRM) in the Federal Register in 2016 requesting public comment on proposed biosafety requirements, including specific provisions for the inactivation of select agents. Until consistently safe and effective procedures for inactivation and sterility testing can be established, select agent strains of *Bacillus anthracis* that have been through inactivation procedures will remain select agents as stated in the FSAP policy.

As a result of this incident, DoD conducted its own investigation concerning performance and accountability. DoD took this matter very seriously and acted with urgency to address this matter within Deputy Secretary of Defense Work's 30-day timeline. DoD will update this notification with timely, accurate, and sufficiently detailed information as appropriate, including after the CDC and internal DoD investigations are complete or if the Department determines that the status regarding Article 7 changes.

More information regarding this matter is available at:

http://www.defense.gov/Portals/1/features/2015/0615_lab-stats/Review-Committee-Report-Final.pdf

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Measles Outbreak:**

On February 10, 2015, the IHR Program was notified of a potential public health emergency of international concern (PHEIC) involving a large multi-state measles outbreak that started in California in December 2014 and spread to at least 6 additional states, including Arizona, Colorado, Nebraska, Oregon, Washington, and Utah.

A provisional total of 147 cases, reported between December 28, 2014 and March 2, 2015, were linked to the outbreak associated with these Disney parks in seven states: (CA 131, AZ 7, CO 1, NE 2, OR 1, UT 3, WA 2). The confirmed cases include Disneyland employees. In addition, other cases visited these Disney parks while infectious in early January. No source case for the outbreak was identified.

Genotyping of patient samples indicated measles virus strain B3, which has also been detected in at least 14 countries and at least 6 U.S. states. Other genotypes reported from U.S. outbreaks in 2015 were D8, and D9; genotypes H1 and D4 were detected in isolated importations.

CDC Division of Viral Diseases provided technical expertise and assisted states with active case investigation, including laboratory confirmation and genotyping, and contact tracing. In addition, the DVD team served as subject matter experts for media interviews, clinician outreach calls, and inquiries from HHS and the general public. CDC's Division of Global Migration and Quarantine (DGMQ) worked with local, state, and international partners, as well as with the airlines to obtain the passenger manifests from the flights to help identify, locate, and interview contacts.

<http://www.cdc.gov/measles/cases-outbreaks.html>

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Lassa Fever:**

On May 25, 2015, the U.S. IHR National Focal Point became aware of a fatal case of Lassa Fever.

On May 25, 2015, PAHO/WHO was informed that the United States Center for Disease Control and Prevention (CDC) and the New Jersey Department of Health had diagnosed and confirmed a fatal case of Lassa fever in a person returning to the United States from Liberia. The patient traveled from Liberia to Morocco to JFK International Airport on May 17, 2015. The patient did not have a fever on departure from Liberia, did not report symptoms such as diarrhea, vomiting, or bleeding during the flight, and when his temperature was taken on arrival in the United States, he did not have a fever at that time. On May 18, 2015, the patient went to a hospital in New Jersey with symptoms of a sore throat, fever, and tiredness. According to the hospital, he was asked about his travel history and he did not indicate travel to West Africa. The patient was sent home the same day, and on May 21, he returned to the hospital when his symptoms worsened. On May 23, the travel history was revealed and the patient was transferred to a treatment center prepared to treat viral hemorrhagic fevers.

Samples submitted to CDC tested positive for Lassa fever on May 25, 2015. Tests for Ebola and other viral hemorrhagic fevers were negative. The patient was in appropriate isolation when he died on May 25, 2015. During the deployment in Newark, New Jersey, CDC worked with public health officials to communicate with the health workers and other personnel from the hospitals, advise on procedures and personal protective equipment, procedures for dealing with the body and the remaining specimens, to generate a list of patient contacts. Those identified as close contacts were monitored for 21 days for symptoms.

<http://www.cdc.gov/media/releases/2015/p0525-lassa.html>

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern***Listeria monocytogenes* infections linked to pre-packaged caramel apples made from whole apples:**

On January 16, 2015, the U.S. National Focal Point was notified of 32 human cases of *Listeria monocytogenes* infection linked to whole apples from Bidart Bros. used in commercially produced, pre-packaged caramel apples.

By February 12, 2015, a total of 35 people infected with the outbreak strains of *Listeria monocytogenes* had been reported from 12 states. Thirty-four ill people were hospitalized, and seven deaths were reported. Listeriosis contributed to at least three of these deaths. A total of 11 (31%) illnesses were pregnancy-related (occurred in a pregnant woman or her newborn infant), with one illness resulting in a fetal loss. Three invasive illnesses (meningitis) were among otherwise healthy children aged 5–15 years. A total of 28 (90%) of the 31 ill people interviewed reported eating commercially produced, prepackaged caramel apples before becoming ill.

CDC and the FDA recommended that consumers not eat commercially produced, prepackaged caramel apples that were recalled or made with Bidart Bros. apples, and retailers should not sell or serve them. CDC and FDA also recommend that consumers not eat any recalled Granny Smith and Gala apples produced by Bidart Bros. This investigation is now closed, and the shelf life of recalled products has passed.

<http://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/>

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern***Listeria monocytogenes* infections linked to Blue Bell Creameries:**

On April 23, 2015, the U.S. National Focal Point was notified of 10 cases of *Listeria monocytogenes* infection linked to ice cream and other frozen products from Blue Bell Creameries.

In March 2015, Blue Bell Creameries of Brenham, Texas, voluntarily recalled certain ice cream products potentially contaminated with *Listeria monocytogenes*. On April 20, 2015, the firm expanded its recall to include all of its products that were currently on the market because they also had the potential to be contaminated with *Listeria monocytogenes*. This recall included ice cream, frozen yogurt, sherbet and frozen snacks made at all Blue Bell facilities.

A total of ten people with listeriosis related to this outbreak were reported in the United States. Illness onset dates ranged from January 2010 to January 2015. Five cases were identified at a single hospital and the other five cases were identified through a retrospective review of the PulseNet database for DNA fingerprints that were similar to isolates collected from Blue Bell ice cream samples. All ten (100%) patients were hospitalized, and three deaths were reported. Several strains of *Listeria monocytogenes* were involved in this outbreak.

The U.S. Food and Drug Administration (FDA) received information regarding international distribution of the recalled products and notified government authorities of all of the following affected countries:

Belize, British Overseas Territories (Anguilla, Bermuda, Montserrat, Tortola, and Turks and Caicos), Chile, China, Dominica, Dominican Republic, Egypt, Haiti, Jordan, Kuwait, Mexico, Oman, Panama, Peru, Philippines, Qatar, St. Kitts and Nevis, Saudi Arabia, Trinidad and Tobago, United Arab Emirates, and Yemen.

FDA and the CDC recommended that consumers not eat recalled Blue Bell brand ice cream or frozen products and institutions and retailers should not sell or serve them. This investigation is now closed. However, people could continue to get sick because recalled products may still be in consumer freezers and consumers unaware of the recalls could eat them. Institutions should not serve and retailers should not sell recalled products.

From the U.S. FDA: <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm>

From the U.S. CDC: <http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html>

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern**Zika virus:**

The U.S. National Focal Point was notified of a case of Zika virus on December 16, 2015.

On December 16, 2015, the Territorial Epidemiologist of the Puerto Rico Department of Health (PRDH) received a report of a laboratory-confirmed case of Zika virus disease in the Commonwealth of Puerto Rico.

The patient was an 80 year-old male resident of Humacao, Puerto Rico, who was hospitalized in the Veterans Administration (VA) Hospital in San Juan, Puerto Rico, in early December 2015. He reported lethargy, diarrhea, anorexia, headache, and body pain that began on November 25. The patient was found to have thrombocytopenia and renal failure in the hospital but recovered and was discharged. Per VA staff, the patient reported no travel history outside of Puerto Rico in the two weeks prior to his illness onset and testing for other etiologies was negative. A blood sample obtained on December 2 was positive for Zika viral RNA by RT-PCR at the Public Health Reference Laboratory for the Department of Veterans Affairs. Subsequent sequencing of the envelope gene was 98-99% homologous with the Asian strain. Sequencing of the patient sample at the CDC confirmed Zika virus.

The Puerto Rico Department of Health interviewed the patient and confirmed no history of travel outside the island in the prior 3 months. Epidemiological investigations were conducted to determine the source of exposure and to identify possible additional cases. Vector control efforts that were initiated, and are still underway, included inspections to identify mosquito breeding sites. The public was also urged to take preventive measures to avoid mosquito bites.

Background:

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. Since then, local transmission has been identified in 21 additional countries and territories in the Americas including the U.S. Virgin Islands. Further expansion of these outbreaks and spread to other countries in the region is likely.

Zika virus is a mosquito-borne flavivirus transmitted primarily by *Aedes aegypti* mosquitoes. This vector also transmits dengue and chikungunya viruses and is found throughout much of the Americas, including parts of the United States. Humans are the primary amplifying host for Zika virus and approximately 20% of infected persons develop symptomatic disease. The most common clinical findings are acute onset of rash and fever. Additional symptoms can include arthralgia, myalgia, and headaches. Mortality and severe disease is rare.

No specific treatment, vaccine, or preventive drug is available. Treatment is palliative and can include rest, fluids, and use of analgesics and antipyretics. Most patients' symptoms improve within one week. Guillain-Barre Syndrome has been reported following Zika virus infections and a possible association between maternal infection with Zika virus and subsequent microcephaly in infants is being investigated. The best way to prevent Zika virus infection is to avoid mosquito bites: use air conditioning or screens when indoors, use insect repellents, and wear long sleeves and pants when outdoors. Persons infected with Zika virus should be protected from mosquito exposure during the first week of illness to prevent further spread of the virus.

On February 1, 2016, the World Health Organization declared a Public Health Emergency of International Concern (PHEIC) because of clusters of microcephaly and other neurological disorders in some areas affected by Zika. As of Feb, 16, 2016, CDC remains actively engaged in response to outbreaks of Zika occurring in the Americas and increased reports of birth defects and Guillain-Barré syndrome in areas affected by Zika.

<http://www.cdc.gov/zika/>

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Summary of Reports: In 2015, the United States submitted two World Organization for Animal Health (OIE) immediate reports for animal disease events that deviated from the normal pattern. These included one low pathogenic notifiable avian influenza report and one highly pathogenic avian influenza (HPAI) report. Event summaries can be found on the OIE website: <http://web.oie.int/wahis/public.php>. Summaries are organized by the year of their occurrence. Even though the OIE removed vesicular stomatitis virus from its OIE-listed diseases for 2015, a significant event occurred in the United States in 2015 and is reported here.

2015 immediate reports:**Notifiable Avian Influenza**

Avian influenza (AI) is caused by influenza type A viruses which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free-flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or "H" proteins, of which there are 16 (H1-H16), and neuraminidase or "N" proteins, of which there are 9 (N1-N9). Many different combinations of "H" and "N" proteins are possible. Each combination is considered a different subtype, and each subtype can be further sub-classified as different strains. AI viruses are identified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens. Any influenza A virus (including H5 and H7 avian influenza viruses) in its high pathogenic form is reportable in birds, but only H5 and H7 low pathogenic avian influenza viral infections in poultry are notifiable as per Chapter 10.4 on avian influenza of the OIE Terrestrial Animal Health Code (2015):

http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_avian_influenza_viruses.htm.

Low Pathogenic Avian Influenza (LPAI), H7N3

OIE Immediate Report March 17, 2015 –Resolved August 18, 2015

Low pathogenic notifiable avian influenza H7N3 was detected in a commercial tom (male) turkey flock located in Merced County, California. The USDA Animal and Plant Health Inspection Service (APHIS) and the California Department of Food and Agriculture (CDFA) completed a comprehensive epidemiological investigation of the event. The turkey flock was depopulated and appropriate cleaning and disinfection (C&D) of the premises completed. All follow-up surveillance and testing for influenza A virus was negative.

Highly Pathogenic Avian Influenza (HPAI), H5N1

OIE Immediate Report January 20, 2015 –Resolved June 16, 2015

HPAI H5N1 was detected in hunter-harvested wild birds in Whatcom County, Washington. The HPAI H5N1 wild bird event (reported to OIE in 2015) was identified as part of the increased avian influenza surveillance of wild birds, and related to the 2014 ongoing H5N8 and H5N2 HPAI events. Required enhanced AI surveillance throughout the United States did not identify any other detections of this novel HPAI EA/AM H5N1-reassortant virus. This novel HPAI EA/AM H5N1-reassortant virus was not found in any poultry, commercial or backyard, anywhere in the United States.

2014 OIE immediate reports resolved in 2015:**Highly Pathogenic Avian Influenza (HPAI), H5N8**

OIE Immediate Report December 16, 2014—Resolved August 17, 2015

USDA APHIS, in conjunction with state departments of agriculture and wildlife, conducted a comprehensive epidemiological investigation and enhanced surveillance (including wild bird surveillance of hunter-harvested birds) in response to the HPAI H5N8 and H5N2 wild bird related events. Novel avian influenza virus of Eurasian

origin (EA-H5N8 clade 2.3.4.4) spread rapidly along wild bird migratory pathways during 2014 -2015. Introduction of this EA-H5N8 virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American (AM) lineage viruses and generated new combinations with genes from both EA and AM origin (or “reassortant” viruses) such as the EA/AM H5N2-reassortant detected in Canada and the United States. These findings are not unexpected as the EA-H5N8 virus continues to circulate. The EA H5 clade 2.3.4.4 viruses are highly pathogenic for poultry.

All control areas have been released and outbreaks concluded the HPAI H5N8 event. The required surveillance in the state and control areas has been completed with negative results for HPAI; the depopulation of infected premises has been completed and appropriate disposal was completed; cleaning and disinfecting of the infected premises has been completed (including, but not limited to, outside areas of premises, equipment, trucks, and other fomites); and no recent HPAI detections through wild bird surveillance have been made.

Highly Pathogenic Avian Influenza (HPAI), H5N2

OIE Immediate Report December 16, 2014—Resolved November 18, 2015

USDA APHIS, in conjunction with state departments of agriculture and wildlife, conducted a comprehensive epidemiological investigation and enhanced surveillance (including wild bird surveillance of hunter-harvested birds) in response to the HPAI H5N8 and H5N2 wild bird related events. Novel avian influenza virus of Eurasian origin (EA-H5N8 clade 2.3.4.4) spread rapidly along wild bird migratory pathways during 2014 -2015.

Introduction of this EA-H5N8 virus into the Pacific Flyway sometime during 2014 has allowed mixing with North American (AM) lineage viruses and generated new combinations with genes from both EA and AM origin (or “reassortant” viruses) such as the EA/AM H5N2-reassortant detected in Canada and the United States. These findings are not unexpected as the EA-H5N8 virus continues to circulate. The EA H5 clade 2.3.4.4 viruses are highly pathogenic for poultry.

All control areas have been released and outbreaks closed in the HPAI H5N2 event. The required surveillance in the state and control areas has been completed with negative results for HPAI; the depopulation of infected premises has been completed and appropriate disposal was completed; cleaning and disinfection of the infected premises has been completed (including, but not limited to, outside areas of premises, equipment, trucks, and other fomites); and no recent HPAI detections through wild bird surveillance have been made.

Other outbreaks:

Vesicular stomatitis virus

Vesicular stomatitis is an insect-transmitted acute disease, primarily of horses, cattle, and pigs, with less frequent infections of sheep and goats, and characterized by the formation of vesicles on the snout, mouth, udder, and feet. The causative agent is vesicular stomatitis virus (VSV), a member of the genus *Vesiculovirus* in the family *Rhabdoviridae*. The OIE removed VSV from its OIE-listed diseases for 2015. Vesicular stomatitis will continue to be a reportable disease in the United States because of its clinical similarity with foot-and-mouth disease (FMD) in cloven-hoofed animals.

The 2015 VSV outbreak in the United States began April 29, 2015, and the last VSV-affected premises was identified in January 2016. To date, a total of 823 VSV-affected premises (New Jersey serotype) have been confirmed or suspected in 8 U.S. states; Arizona (36 premises in 3 counties), Colorado (441 premises in 36 counties), Nebraska (38 premises in 10 counties), New Mexico (52 premises in 13 counties), South Dakota (50 premises in 7 counties), Texas (4 premises in 4 counties), Utah (56 premises in 8 counties), and Wyoming (146 premises in 10 counties). Currently, there is one premises remaining under quarantine in one state (Colorado).

Form C
BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2016

Department of Health and Human Services (HHS) Open Government Plan http://www.hhs.gov/open/plan	The key principles of Open Government are transparency, collaboration, and participation.
HHS Strategic Plan 2014-2018 http://www.hhs.gov/secretary/about/priorities/priorities.html	The plan describes HHS' work to address complex, multifaceted, and ever-evolving health and human service issues. Goal 4 of this plan is to Increase Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.
National Institutes of Health (NIH) Data Sharing Policy and Implementation Guide http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm	This guidance provides the National Institutes of Health (NIH) policy statement on data sharing and additional information on the implementation of this policy.
Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data http://www.cdc.gov/maso/Policy/ReleasingData.pdf	Public health and scientific advancement are best served when data are shared with public health agencies and academic researchers in an open, timely, and appropriate way.
The Journal <i>Emerging Infectious Diseases</i> http://wwwnc.cdc.gov/eid/	<i>Emerging Infectious Diseases</i> is an open access, peer-reviewed journal published by the Centers for Disease Control and Prevention (CDC).
The Morbidity and Mortality Weekly Report (MMWR) http://www.cdc.gov/mmwr/	CDC's primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access.
The Excellence in Science Committee (EISC) at the CDC http://www.cdc.gov/od/science/excellence/	The EISC fosters, supports, and protects an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health.
CDC Office of Science Quality (OSQ) http://www.cdc.gov/od/science/quality/	The OSQ is responsible for increasing the impact of CDC research and science by promoting standards and recommended practices for scientific quality, relevance, credibility, transparency, and utility within the agency and throughout the public health community (e.g., authorship, scientific clearance, peer review, and extramural research policies).
Advancing Excellence and Integrity of CDC Science http://www.cdc.gov/od/science/	The Office of the Associate Director for Science's mission is to strengthen the quality, integrity, and relevance of CDC's science and health impact
Office of Scientific Integrity (OSI) http://www.cdc.gov/od/science/integrity/	OSI ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and

	ethical domestic and international workforce at CDC.
Public Health Image Library (PHIL) http://phil.cdc.gov/	The PHIL offers an organized, electronic gateway to CDC images for reference, teaching, presentation, and public health messages; open access.
U.S. Food and Drug Administration (FDA) Publications Database http://www.accessdata.fda.gov/scripts/publications/	An actively updated and searchable research publications database for all FDA publications.
FDA Office of Science and Engineering Laboratories (OSEL) Annual Report http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm109778.htm	The OSEL Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and research seminars for the fiscal year.
FDA Center for Biologics Evaluation and Research (CBER) http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm	This CBER website provides links to the strategic plan for regulatory science and research, general information about research programs, as well as highlights from selected research publications.
PubMed Central (PMC) http://www.ncbi.nlm.nih.gov/pmc/	PMC is the National Library of Medicine's digital archive. Final peer-reviewed manuscripts that arise from NIH funds are accessible to the public on PMC no later than twelve months after publication; open access.
The National Institutes of Health (NIH) Public Access Policy http://publicaccess.nih.gov/policy.htm	The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.
Agricultural Research Magazine http://www.ars.usda.gov/is/AR/	The Agricultural Research Magazine is the USDA's science magazine published by the Agricultural Research Service (ARS); open access.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2016

Relating to	Legislation	Regulations	Other measures ⁹	Amended since last year
(a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	Yes	Yes	Yes	No
(b) Exports of micro-organisms¹⁰ and toxins	Yes	Yes	Yes	Yes [1]
(c) Imports of micro-organisms¹¹ and toxins	Yes	Yes	No	Yes [2]
(d) Biosafety¹¹ and biosecurity¹²	Yes	Yes	Yes	Yes [3]

[1] Amendments re: (b) Exports of micro-organisms and toxins:

Implementation of the Australia Group (AG) November 2013 Intersessional Decisions

This regulation was published in the June 16, 2015 Federal Register (80 FR 34266) and amends the Commerce Control List (CCL) entry in the Export Administration Regulations (EAR) that controls certain human and zoonotic pathogens and toxins, and removes the CCL entry that controls certain animal pathogens to reflect the merger of two AG common control lists based on recommendations presented at the Australia Group (AG) Intersessional meeting in 2013, and adopted in 2014. As a result, the AG “List of Animal Pathogens for Export Control” was merged with the AG “List of Biological Agents for Export Control,” creating a single AG common control list for these items (i.e., the AG “List of Human and Animal Pathogens and Toxins for Export Control”). The scope of the controls on these human and animal pathogens and toxins was not affected by the merger of the two lists into a single AG common control list. This rule also makes conforming amendments to other provisions in the EAR to reflect these changes. This rule does not contain changes based on the understandings reached at the June 2014 AG Plenary meeting, because no amendments to the EAR were required as a result of these understandings.

<https://www.gpo.gov/fdsys/pkg/FR-2015-06-16/pdf/2015-14471.pdf>

Implementation of the Australia Group (AG) November 2013 Intersessional Decisions; Correction

This technical corrections rule was published in the September 18, 2015 Federal Register (80 FR 34266) to amend the Export Administration Regulations (EAR) to correct typographical errors contained in a final rule published in the Federal Register on June 16, 2015 (80 FR 34266). The Note to ECCN 1C351.a.4 in that final rule incorrectly referenced ECCN 1C352.a.4, instead of ECCN 1C351.a.4. This rule corrects the Note to ECCN 1C351.a.4 to read as follows: “Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.” The corrections to this Note do not affect the

⁹ Including guidelines.

¹⁰ Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.

¹¹ In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.

¹² In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

scope of the controls described in ECCN 1C351.a.4.

<https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23500.pdf>

[2] Amendments re: (c) Imports of micro-organisms and toxins

Federal Select Agency Program Policy Statement: When APHIS and CDC Import Permits Not Required for the Importation or Interstate Transportation of Select Agents

<http://www.selectagents.gov/regpermits.html>

[3] Amendments re: (d) Biosafety and biosecurity

Federal Select Agent Program (FSAP) Policy Statement: Inactivated *Bacillus anthracis*

Although non-viable select agents are excluded from the select agent regulations, it has been observed that some inactivation protocols previously used may not inactivate *Bacillus anthracis* spores completely, necessitating issuance of this policy statement. Unless waived by the Animal and Plant Health Inspection Service (APHIS) Administrator or Department of Health and Human Services (HHS) Secretary, it is the policy of the FSAP that all vegetative cell and spore preparations of *Bacillus anthracis* strains regulated as select agents that were subject to an inactivation procedure on or after **June 2, 2015** are considered a select agent and the storage, transfer, or work with this material must comply with regulations found at 42 CFR 73 and 9 CFR 121 until a more comprehensive protocol for inactivation of *B. anthracis* can be established and validated. This time period was selected based on the date the Federal Select Agent Program (FSAP) issued a moratorium to entities that produces and ships inactivated *B. anthracis* to other laboratories. Possession of such material by an entity not registered to possess the regulated strain of *B. anthracis* or located in a room not listed on a registered entity's registration must be reported within 24 hours of discovery to the FSAP. Additional information is available at

http://www.selectagents.gov/policystatement_bacillus.html.

New White House Memorandum on Biosafety and Biosecurity Measures

On October 29, 2015, the White House released a memorandum from Assistants to the President John Holdren and Lisa Monaco on the next steps to enhance biosafety and biosecurity in the United States. The memo highlights the conduct of parallel federal and broad stakeholder reviews to generate specific recommendations to strengthen the U.S. government's biosafety and biosecurity practices and oversight system

[\(https://www.whitehouse.gov/sites/default/files/docs/10-2015_biosafety_and_biosecurity_memo.pdf\)](https://www.whitehouse.gov/sites/default/files/docs/10-2015_biosafety_and_biosecurity_memo.pdf)

Federal Experts Security Advisory Panel and Fast Track Action Committee on the Select Agent Regulations

On October 29, 2015, the United States government released two sets of recommendations and implementation plans from the Federal Experts Security Advisory Panel (FESAP, which conducted an internal U.S. Government review of biosafety and biosecurity practices) and from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR, which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories). Recommendations made by both the FESAP and FTAC-SAR address culture of responsibility, oversight, outreach and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins. More information is available on the FESAP website at: <http://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx>.

The U.S. Government has developed a plan to implement the FESAP and FTAC-SAR recommended actions, available at: <http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf>. The U.S. Government expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities. The Administration is committed to fostering progress in the life sciences while

ensuring that work is conducted in a safe and secure manner. A summary is available at:
<http://www.phe.gov/s3/Documents/fesap-ftac-factsheet.pdf>

Workshop on Stakeholder Engagement on the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)

On September 24, 2014, the USG released the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). The Policy addresses institutional oversight of DURC, which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable. The White House Office of Science and Technology Policy and the National Institutes of Health co-hosted a public workshop on July 22, 2015, for institutional stakeholders to discuss implementation of the 2014 policy; to inform and engage stakeholders; to collect feedback about resources needed for implementation; and to discuss stakeholder experiences, challenges, and innovative practices. Information about the workshop and DURC educational materials are available at:

<http://www.phe.gov/about/OPP/DURCworkshop/Pages/overview.aspx>

Form F
BWC - Confidence Building Measure

Declaration of Past Activities in Offensive and/or Defensive
Biological Research and Development Programmes

United States of America

April 15, 2016

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

- 1. Date of entry into force of the Convention for the State party**
26 March 1975
- 2. Past offensive biological research and development programmes:**
Nothing new to declare

Form G
BWC - Confidence Building Measure

Declaration of Vaccine Production Facilities

United States of America

April 15, 2016

Declaration of vaccine production facilities

The U.S. Food and Drug Administration publishes a current list of human vaccines licensed in the United States, including associated production facilities. This list is available at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

Data provided on CBM Form G are excerpted from the publicly available website listed above (as accessed on February 3, 2016). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

1. Name of facility

Barr Laboratories, Inc.

2. Location (Mailing Address)

1235 Mays Mill Road, Forrest, Virginia 24551

3. General description of the types of diseases covered:

Acute respiratory disease caused by Adenovirus Type 4 and Type 7

Vaccines: Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

1. Name of facility

Emergent BioDefense Operations Lansing, Inc.

2. Location (Mailing Address)

3500 N. Martin Luther King Jr. Boulevard, Lansing, Michigan 48906

3. General description of the types of diseases covered:

Anthrax disease caused by *Bacillus anthracis*

Vaccines: Anthrax Vaccine Adsorbed - [BioThrax]

1. Name of facility

MassBiologics

2. Location (Mailing Address)

University of Massachusetts Medical School, Boston, Massachusetts 02130

3. General description of the types of diseases covered:

Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*.

Vaccines: Tetanus and Diphtheria Toxoids Adsorbed

Declaration of vaccine production facilities

1. Name of facility

Merck Sharp & Dohme Corp.

2. Location (Mailing Address)

PO Box 1000, UG2D-68, North Wales, Pennsylvania 19454

3. General description of the types of diseases covered:

Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV); Measles; Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

Vaccines:

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B (Recombinant) Vaccine - [COMVAX]

Hepatitis A Vaccine, Inactivated - [VAQTA]

Hepatitis B Vaccine (Recombinant) - [Recombivax HB]

Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant [Gardasil]

Human Papillomavirus 9-valent Vaccine, Recombinant - [GARDASIL 9]

Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]

Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]

Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]

Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]

Varicella Virus Vaccine Live - [Varivax]

Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

1. Name of facility

Organon Teknika Corporation, LLC

2. Location (Mailing Address)

100 Rodolphe Street, Building 1300, Durham, North Carolina 27712

3. General description of the types of diseases covered:

For the prevention of tuberculosis

Vaccines: BCG Live [BCG Vaccine]

Declaration of vaccine production facilities

1. Name of facility

Protein Sciences Corporation

2. Location (Mailing Address)

1000 Research Parkway, Meriden, Connecticut 06450-7159

3. General description of the types of diseases covered:

Disease caused by influenza virus subtypes A and B

Vaccines: Influenza vaccine for subtypes A and B, (Flublok)

1. Name of facility

Sanofi Pasteur Biologics Co.

2. Location (Mailing Address)

38 Sidney Street, Cambridge, Massachusetts 02139

3. General description of the types of diseases covered:

Smallpox disease

Vaccines: Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

1. Name of facility

Wyeth Pharmaceuticals, Inc.

2. Location (Mailing Address)

Pfizer, Inc., 401 N. Middletown Road, Pearl River, New York 10965

3. General description of the types of diseases covered:

Invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F and 23F; and invasive disease caused by *Neisseria meningitidis* serogroup B.

Vaccines:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]

Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Declaration of vaccine production facilities

1. Name of facility

Sanofi Pasteur, Inc.

2. Location (Mailing Address)

Discovery Drive, Swiftwater, Pennsylvania 18370

3. General description of the types of diseases covered:

Diphtheria caused by *Corynebacterium diphtheriae*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcmia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

Vaccines:

Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]

Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)

Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)

Influenza Virus Vaccine, H5N1

Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra]

Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®- A/C/Y/W-135]

Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]

Tetanus Toxoid for Booster Use Only

Yellow Fever Vaccine - [YF-VAX®]

Biological Select Agents and Toxins

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations. Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: <http://www.selectagents.gov>.

HHS Select Agents and Toxins

Abrin

Botulinum neurotoxins

Botulinum neurotoxin-producing species of *Clostridium*

Cercopithecine herpesvirus 1 (Herpes B virus)

Clostridium perfringens epsilon toxin

Coccidioides posadasii/Coccidioides immitis

Conotoxins

Coxiella burnetii

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol

Eastern Equine Encephalitis virus

Ebola virus

Francisella tularensis

Lassa fever virus

Marburg virus

Monkeypox virus

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

Ricin

Rickettsia prowazekii

Rickettsia rickettsii

Saxitoxin

Shiga-like ribosome inactivating proteins

Shigatoxin

South American Haemorrhagic Fever viruses: Flexal, Machupo, Guanarito, Sabia, Junin

Staphylococcal enterotoxins

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses: Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever, Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

Yersinia pestis

OVERLAP Select Agents and Toxins

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins

Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycincola (formerly *Pyrenophaeta glycines*)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var *zeae*
Synchytrium endobioticum
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix A

NIAID Category A, B, and C Priority Pathogens

The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens is available at:

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx>

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf>

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category A Priority Pathogens

Bacillus anthracis (anthrax)

Clostridium botulinum toxin (botulism)

Yersinia pestis (plague)

Variola major (smallpox) and other related pox viruses

Francisella tularensis (tularemia)

Viral hemorrhagic fevers

Arenaviruses (LCMV, Junin virus, Machupo virus, Guanarito virus, Lassa virus)

Bunyaviruses (Hantaviruses, Rift Valley Fever virus)

Flaviruses (Dengue virus)

Filoviruses (Ebola, Marburg viruses)

Category B pathogens are the second highest priority organisms/biological agents. They

- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements for diagnostic capacity and enhanced disease surveillance

Category B Priority Pathogens

Burkholderia pseudomallei

Coxiella burnetii (Q fever)

Brucella species (brucellosis)

Burkholderia mallei (glanders)

Chlamydia psittaci (Psittacosis)

Ricin toxin (from *Ricinus communis*)

Epsilon toxin of *Clostridium perfringens*

Staphylococcus enterotoxin B

Typhus fever (*Rickettsia prowazekii*)

Food- and Waterborne Pathogens

- Bacteria: Diarrheagenic *E.coli*, Pathogenic *Vibrio*, *Shigella* species, *Salmonella*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*

- Viruses: Caliciviruses, Hepatitis A virus

- Protozoa: *Cryptosporidium parvum*, *Cyclospora cayatanensis*, *Giardia lamblia*, *Entamoeba histolytica*, Toxoplasma
- Fungi: Microsporidia

Additional viral encephalitides: West Nile Virus, LaCrosse virus, California encephalitis virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Japanese Encephalitis Virus, Kyasanur Forest Virus

Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of

- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

Category C Priority Pathogens

Emerging infectious disease threats such as Nipah virus and additional hantaviruses

Tickborne hemorrhagic fever viruses (Crimean-Congo Hemorrhagic fever virus)

Tickborne encephalitis viruses

Yellow fever

Tuberculosis, including drug-resistant TB

Influenza

Other Rickettsias

Rabies

Prions

Chikungunya virus

Severe acute respiratory syndrome associated coronavirus (SARS-CoV)

Coccidioides immitis

Coccidioides posadasii

Antimicrobial resistance, excluding research on sexually transmitted organisms¹³

- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations
- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

¹³ NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms: Bacterial vaginosis, Chlamydia trachomatis, Cytomegalovirus, Granuloma inguinale, *Hemophilus ducreyi*, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, *Neisseria gonorrhoea*, *Treponema pallidum*, *Trichomonas vaginalis*

Compiled list of microorganisms and toxins used for biodefense research

MICROORGANISM	CATEGORY
African horse sickness virus	USDA Select Agent
African swine fever virus	USDA Select Agent
Avian influenza virus (highly pathogenic)	USDA Select Agent
<i>Bacillus anthracis</i>	Overlap Select Agent + NIAID Category A
<i>Bacillus anthracis</i> (inactivated)	Simulant
<i>Bacillus anthracis</i> Pasteur strain	Overlap Select Agent
<i>Bacillus anthracis</i> Sterne	Simulant
<i>Bacillus anthracis</i> (killed)	Simulant
<i>Brucella abortus</i>	Overlap Select Agent
<i>Brucella melitensis</i>	Overlap Select Agent
<i>Brucella suis</i>	Overlap Select Agent
<i>Burkholderia mallei</i>	Overlap Select Agent
<i>Burkholderia mallei</i> (killed)	Simulant
<i>Burkholderia pseudomallei</i>	Overlap Select Agent
Chapare virus	HHS Select Agent
Classical swine fever virus	USDA Select Agent
Clostridium species producing botulinum neurotoxin	HHS Select Agent + NIAID Category A
<i>Coxiella burnetti</i>	HHS Select Agent
<i>Coxiella burnetti</i> (inactivated)	Simulant
<i>Coxiella burnetti</i> (killed)	Simulant
Crimean-Congo hemorrhagic fever virus	HHS Select Agent
Dengue virus	NIAID Category A
Dengue virus (inactivated)	Simulant
Eastern equine encephalitis virus	HHS Select Agent
Ebola virus	HHS Select Agent + NIAID Category A
Ebola virus (inactivated)	Simulant
Foot-and-mouth disease virus	USDA Select Agent
<i>Francisella philomiragia</i>	Simulant
<i>Francisella tularensis</i>	HHS Select Agent + NIAID Category A
<i>Francisella tularensis</i> (killed)	Simulant
Goatpox virus	USDA Select Agent
Guanarito virus	HHS Select Agent + NIAID Category A
Hantaviruses	NIAID Category A
Hendra virus	Overlap Select Agent
Influenza A virus, reconstructed replication-competent pandemic 1918 strains	HHS Select Agent
Junin virus	HHS Select Agent + NIAID Category A
Kyasanur Forest disease virus	HHS Select Agent
Lassa virus	HHS Select Agent + NIAID Category A
Lujo virus	HHS Select Agent
Lumpy skin disease virus	USDA Select Agent
Lymphocytic choriomeningitis virus	NIAID Category A
Machupo virus	HHS Select Agent + NIAID Category A

Marburg virus	HHS Select Agent + NIAID Category A
Monkeypox virus	HHS Select Agent
<i>Mycoplasma capricolum</i>	USDA Select Agent
<i>Mycoplasma mycoides</i>	USDA Select Agent
Newcastle disease virus	USDA Select Agent
Nipah virus	Overlap Select Agent
Peste-des-petits-ruminants virus	USDA Select Agent
Omsk hemorrhagic fever virus	HHS Select Agent
<i>Phoma glycincola</i>	PPQ Select Agent
<i>Rathayibacter toxicus</i>	PPQ Select Agent
<i>Rickettsia prowazekii</i>	HHS Select Agent
Rift Valley fever virus	Overlap Select Agent + NIAID Category A
Sabia virus	HHS Select Agent
Severe acute respiratory syndrome-related coronavirus	HHS Select Agent
Sheep pox virus	USDA Select Agent
Tick-borne encephalitis complex flavivirus, Far Eastern subtype	HHS Select Agent
Tick-borne encephalitis complex flavivirus, Siberian subtype	HHS Select Agent
Variola major virus	HHS Select Agent + NIAID Category A
Variola minor virus	HHS Select Agent
Venezuelan equine encephalitis virus	Overlap Select Agent
<i>Yersinia pestis</i>	HHS Select Agent + NIAID Category A
<i>Yersinia pestis</i> (killed)	Simulant
TOXINS	
CATEGORY	
Abrik	HHS Select Toxin
Alpha conotoxins	HHS Select Toxin
Botulinum neurotoxins	HHS Select Toxin
Diacetoxyscirpenol	HHS Select Toxin
Ricin	HHS Select Toxin
Saxitoxin	HHS Select Toxin
Staphylococcal enterotoxins A, B, C, D, E subtypes	HHS Select Toxin
T-2 toxin	HHS Select Toxin
Tetrodotoxin	HHS Select Toxin